No. 24-1365

In the United States Court of Appeals for the District of Columbia Circuit

DOCTORS FOR DRUG POLICY REFORM; BRYON ADINOFF, DR.,

Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents

On Petition for Review of Orders of the Drug Enforcement Administration (Oct. 28, 2024 and Nov. 25, 2024)

PETITIONERS' APPENDIX
VOLUME 5 OF 6
App.1380 to App.1477

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Dated: February 17, 2025

Respectfully submitted,

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September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

Subject: Notice of Appearance

Dear Administrator Milgram:

Please take notice that Vicente LLP, requests the opportunity to appear on behalf of Sensible Colorado in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule"), Docket No. DEA-1362, currently scheduled for December 2, 2024, at 9:00am E.T., per 89 Fed. Reg. 70,148.

(A) Sensible Colorado has standing to participate in the hearing. 21 C.F.R. § 1300.01(b) allows that "any person adversely affected or aggrieved by any rule or proposed rule issuable" under 21 U.S.C. § 811 has standing to appear at the hearing for the Proposed Rule ("Interested Person").[1] Sensible Colorado is an Interested Person and falls within the Controlled Substances Act's ("CSA") zone of interests. Further, Sensible Colorado will be directly and adversely affected or aggrieved by the Proposed Rule if finalized. Sensible Colorado's status as an Interested Person is further detailed in the enclosed submission.

(B) Among other things, Sensible Colorado desires to be heard, has unique expertise, and would provide invaluable insights into: (i) medical and scientific research involving marijuana, including as it relates to veterans' access; (ii) marijuana's medical efficacy, including the use of marijuana in the practice of medicine in the U.S. under state-legal programs (particularly in Colorado); (iii) the effects of the Proposed Rule on members of Sensible Colorado who are minority-owned/small businesses and on members whose communities have been impacted by the war on drugs; (iv) the abuse potential, public health risks, and illicit market for marijuana; (v) marijuana's usefulness in replacing other more harmful substances (i.e. alcohol and opioids); (vi) the specific ways Sensible Colorado's members will be adversely affected and aggrieved by the Proposed Rule, if finalized; and (vii) the practical consequences of rescheduling marijuana.[2] Further details about the objections or issues on which Sensible Colorado desires to be heard are provided in the enclosed submission.

(C) Since 2004, Sensible Colorado has represented Colorado medical marijuana providers and patients who are active participants in and around the state-legal marijuana industry and who

[1] Pursuant to 21 C.F.R. § 1300.01(b), "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."
[2] "DOJ is seeking comment on the practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks." 89 Fed. Reg. 44621 (May 21, 2024).

will be, in addition to Sensible Colorado itself, directly and adversely affected by the Proposed Rule, if finalized. Sensible Colorado is thus uniquely situated to assist the Drug Enforcement Administration's ("DEA") administrative decision making. Sensible Colorado has extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated medical marijuana marketplace. DEA has sought comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. Sensible Colorado is particularly well-suited to provide this insight, as it represents medical marijuana providers and patients in Colorado, has worked to advance medical marijuana policies nationwide, and is a leader among states in regulating a successful medical marijuana market. Sensible Colorado's positions with regard to the particular objections or issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to:

Timothy D. Swain
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Boston, MA 02199
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Respectfully yours,

/s/ Timothy D. Swain
Timothy D. Swain, Esq.

Vicente.

September 30, 2024

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: DEA Federal Register
Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Request to Participate in a Hearing & Notice of Appearance
Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597, Docket No. DEA-1362

Administrator Milgram:

Pursuant to 21 C.F.R. § 1308.44(b) and § 1316.48, Sensible Colorado submits, as an Interested Person, this Request to Participate in a Hearing and Notice of Appearance. Sensible Colorado is submitting declarations to support the expert and fact witness testimony that would be provided by Sensible Colorado for the December 2, 2024, hearing being held pursuant to 89 Fed. Reg. 70,148 ("Notice of Hearing"), as enclosures to this Request to Participate in a Hearing & Notice of Appearance.

Sensible Colorado's members include Colorado medical marijuana patients (including veterans), small businesses, and physicians who have recommended medical marijuana to patients, seeing its benefits firsthand. Sensible Colorado and its members are Interested Persons within the zone of interests and will be adversely affected or aggrieved by this proposed rule, entitled Schedules of Controlled Substances: Rescheduling of Marijuana, if finalized. *See* 89 Fed. Reg. 44,597 (May 21, 2024) (the "Proposed Rule").

In the context of this Proposed Rule, it is Sensible Colorado's position that medical, scientific, and other evidence supports removing "marijuana", "marijuana extract", and "naturally derived delta-9-tetrahydrocannabinols" from schedule I of the CSA.

Sensible Colorado has standing to participate in the hearing. Among other things, Sensible Colorado has unique expertise and provides invaluable insights into: (i) medical and scientific research involving marijuana, including as it relates to veterans' access; (ii) marijuana's medical efficacy, including the use of marijuana in the practice of medicine in the U.S. under state-legal programs (particularly in Colorado); (iii) the effects of the Proposed Rule on members of Sensible Colorado who are minority-owned/small businesses and on members whose communities have been impacted by the war on drugs; (iv) the abuse potential, public health risks, and illicit market for marijuana; (v) marijuana's usefulness in replacing other more harmful substances (i.e. alcohol and opioids); (vi) the specific ways Sensible Colorado's members will be adversely affected and

aggrieved by the Proposed Rule, if finalized; and (vii) the practical consequences of rescheduling marijuana. Sensible Colorado is prepared to present expert testimony on these issues and the placement of marijuana on the CSA's schedules. Sensible Colorado's testimony would materially assist the DEA ALJ in preparing a sound and well-supported administrative decision.

A. Background

On May 21, 2024, DOJ issued a Notice of Proposed Rulemaking, Schedules of Controlled Substances: Rescheduling of Marijuana. Proposed Rule at 44,597. In the Notice of Hearing DEA requested that interested persons who wish to participate in the hearing submit requests to DEA on, or before 11:59pm Eastern Time on September 30, 2024. This request to participate in a hearing is timely filed.

This request to participate serves to inform DEA that Sensible Colorado is an Interested Person and requests the ability to participate in DEA's rulemaking process to the fullest extent possible, including at the December 2, 2024, hearing that DEA has granted.

B. Who Is Sensible Colorado

Sensible Colorado is a prominent nonprofit (501(c)(3)) organization, based in Denver, CO, promoting the legal and regulatory framework supporting medical marijuana patients in Colorado together with its members. Founded in 2004 in response to police enforcement against medical marijuana patients, Sensible Colorado collaborates closely with state, federal, and international policymakers, regulatory agencies, researchers, standards organizations, accreditation bodies, and industry stakeholders to foster a viable, safe, and regulated medical marijuana program with a focus on public health and safety and consumer protection.

Sensible Colorado is particularly focused on areas such as product safety, industry standards, legislative advocacy, education, research, and testing within the marijuana industry. It provides its members with critical information on regulatory changes, market trends, and legal challenges. Sensible Colorado has a vested interest in seeing that its members have access to safely regulated medical marijuana and in ensuring that their use of medical marijuana products is safe, tested, overseen by qualified physicians, and medicinally beneficial.

For 20 years, Sensible Colorado has spent extensive time, money, and other resources to advocate for a regulated, responsible medical marijuana program that supports Colorado patients with debilitating medical conditions. Sensible Colorado is uniquely situated to provide information at the hearing given its longstanding advocacy in one of the nation's longest running state-legal medical marijuana programs. Sensible Colorado's interests and resource expenditures would be at risk if Sensible Colorado were not permitted to participate in the formal rulemaking process to the fullest extent permitted by law.

The Proposed Rule directly affects Sensible Colorado, and it affects Sensible Colorado through the impact it has on the organization's members. Specifically, Sensible Colorado's advocacy efforts will be affected by the Proposed Rule. Similarly, its members will be impacted by the Proposed Rule, if finalized, by, among other things, (1) the criminal penalties applicable to their

state-legal medical marijuana activities; (2) the continuing barriers applicable to the scientific and medical communities participating in state-legal medical marijuana programs; (3) the prices they pay for medical marijuana due to the implications of 26 U.S. Code § 280E ("280E"); and (4) the implications of using state-legal medical marijuana on employment, housing, parental rights, and immigration status. If DEA eschews the Proposed Rule and decides that marijuana should remain on schedules I or II, that decision would also adversely affect Sensible Colorado and its members for the same reasons stated above, particularly as it relates to tax relief for state-legal medical marijuana businesses.

C. Objections Or Issues Concerning Which Sensible Colorado Desires to Be Heard

The Proposed Rule represents a sea change in how the federal government proposes to control marijuana, including how it may be accessed by patients who rely on the substance for effective medical treatment. As DEA is aware, marijuana is currently categorized as a schedule I substance, making it subject to the most stringent controls. Schedule I substances, according to DEA's classification, have no currently accepted medical use and a high potential for abuse. Some examples of schedule I drugs are heroin, LSD, ecstasy, and peyote.[3]

Sensible Colorado maintains that marijuana does not belong in schedule I, particularly given its accepted medical utility and relatively low potential for abuse, even as compared to some unscheduled substances, such as alcohol.[4] As detailed in the Proposed Rule, the Department of Health and Human Services ("HHS") conducted a comprehensive scientific and medical evaluation of the appropriate classification of marijuana and recommended that marijuana be transferred to schedule III. 89 Fed. Reg. at 44,600. Specifically, HHS concluded that marijuana has a potential for abuse less than the other substances in schedules I and II; that marijuana has a currently accepted medical use in treatment in the United States; and that the abuse of marijuana may lead to moderate or low physical dependence or psychological dependence. Id. Marijuana's medical use in treatment is demonstrated by the over six million Americans registered as medical marijuana patients in 38 states, the District of Columbia, and the four territories hat have legalized the use of medical marijuana, to treat certain health conditions, including chronic pain.[5] A growing number of organizations with expertise on medical efficacy (including but not limited to the National Academies of Sciences, Engineering, Medicine, the Center for Disease Control, and the National Institute on Drug Abuse) recognize marijuana's medical use and that there is credible scientific evidence supporting its treatment for conditions like chronic pain and nausea and vomiting. In contrast, schedule II substances are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of schedule II drugs are cocaine, methamphetamine, methadone, and oxycodone. Many schedule II substances are known drivers of the country's

[3] DEA, Drug Scheduling, https://www.dea.gov/drug-information/drug-scheduling (Last accessed September 26, 2024).
[4] Jonathan P. Caulkins, *Changes in Self-Reported Cannabis Use in the United States from 1979 to 2022*, 119 Addiction, pg. 1648 (May 22, 2024).
[5] *2022 State of the States Report: An Analysis of Medical Cannabis Access in the United States*, Americans for Safe Access, https://assets.nationbuilder.com/americansforsafeaccess/pages/27187/attachments/original/1675362731/StateoftheStates22_P5.pdf?1675362731 (Last accessed on Sep. 25, 2024).

opioid epidemic. Over the past 20 years, Sensible Colorado's members have included thousands of patients who have safely used marijuana as medicine under Colorado's regulated medical marijuana program. In light of this, Sensible Colorado agrees that marijuana has a currently accepted medical use in treatment in the U.S. and a relatively low abuse potential, and therefore should be removed from schedule I.[6]

The public health risks of marijuana are lower than those of the "comparator substances controlled" under schedules I through V. Sensible Colorado's participation in the administrative hearing process would demonstrate that marijuana does not compare to the public health risks of substances in schedules I and II like heroin (schedule I), cocaine (schedule II), or fentanyl (schedule II). *See* Proposed Rule at 44,614 (discussing HHS' recommendation on this point); *see also id.* at 44,618 (noting that heroin, cocaine, and fentanyl were considered "comparator substances controlled" under schedules I and II). According to data from the Centers for Disease Control and Prevention ("CDC"), heroin, cocaine, and fentanyl are responsible for tens of thousands of fatalities in the United States annually.[7] In fact, DEA has launched a public awareness campaign that even "One Pill" of fentanyl "Can Kill," noting that two milligrams of fentanyl (an amount smaller than a pencil tip) can be deadly.[8] Given its deadly nature, the risk profile of fentanyl—a schedule II substance—dwarfs that of marijuana. DEA itself recognizes that zero deaths have been associated with marijuana overdose.[9] Indeed, in considering lethal dose values that indicate the risk of inducing death and representing a significant level of harm, marijuana is considerably less dangerous than substances in schedules III, IV, and V, and unscheduled substances like nicotine[10] and caffeine[11].

Sensible Colorado's participation in the hearing would also demonstrate that marijuana poses less public health risks than substances in schedules III through V and is less harmful than alcohol and tobacco, neither of which is controlled under the CSA. Marijuana poses less public health risk, including a lower abuse potential and lower recognized risk to children, than many drugs in schedules III-V, such as ketamine and benzodiazepines, which are highly addictive, highly abusable, and readily available for prescription through telemedicine. Like opioids, benzodiazepines are subject to prescription drug misuse and have been associated with increased

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[6] Statement from President Biden on Marijuana Reform, 2022 DAILY COMP. PRES. DOC. 883 (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/ (hereinafter Statement on Marijuana Reform).

[7] CDC, Provisional Drug Overdose Death Counts, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (Last accessed September 26, 2024).

[8] DEA, One Pill Can Kill, https://www.dea.gov/onepill (Last accessed September 26, 2024).

[9] DEA, Marijuana/Cannabis: Drug Fact Sheet at 3 (April 2020), https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf (Last accessed September 26, 2024).

[10] *PubChem Coumpound Summary for CID 89594, Nicotine*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION,https://pubchem.ncbi.nlm.nih.gov/compound/89594#section=Toxicity (Last accessed Sep. 25, 2024).

[11] *PubChem Coumpound Summary for CID 2519, Caffeine*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION, https://pubchem.ncbi.nlm.nih.gov/compound/2519#section=UN-Classification (last visited on Sep. 25, 2024).

risk of opioid overdose and opioid-related mortality in adolescents and young adults.[12] Sensible Colorado is also prepared to discuss how illicit, unregulated, marijuana and marijuana products pose a greater public health risk than state-legal medical marijuana and marijuana products.

The HHS analysis on relative abuse potential, reproduced below, inappropriately concludes that schedule III is the appropriate classification for marijuana:

> *[T]he rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.*
>
> *There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, each substance has associated with it a different population that abuses the substance, a different prevalence of abuse, and a different profile of several adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases, and when these rankings often do not align with the scheduling placement of the comparators under the CSA.* ***To address these challenges, we evaluate the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III.***[13]

Sensible Colorado does not believe this analysis is sufficient, and it intends to provide testimony on the low physical and psychological dependence of marijuana relative to substances in schedules III through V. In particular, the analysis does not properly compare marijuana to benzodiazepines, antipsychotics, and cough medicines containing codeine, the abuse of which results in significant physiological and psychological dependence. However, it is important to note that the Proposed Rule does recognize that the public health risk of benzodiazepines is substantially greater than the risk presented by marijuana. At the very least, the evidence will show that compared to benzodiazepines, antipsychotics, and cough medicines containing codeine, abuse of marijuana leads to limited physical dependence or psychological dependence relative to substances in schedule IV and V. Sensible Colorado will present expert witness testimony from Dr. Corey Burchman and Dr. Alan Shackelford to support the forgoing.

Dr. Corey Burchman is a neuro-anesthesiologist, obstetrical anesthesiologist, and former U.S. Navy physician, who serves as a key advocate in the Coalition for Cannabis Scheduling Reform.

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[12] Toce MS, Michelson KA, Hudgins JD, Olson KL, Bourgeois FT. *Trends in Benzodiazepine Prescribing for US Adolescents and Young Adults From 2008 to 2019*. JAMA Pediatr. 2022;176(3):312–313. doi:10.1001/jamapediatrics.2021.5122; FDA, FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faerspublic-dashboard (last visited Mar. 20, 2023) (According to that data, approximately 3 percent or less of drug abuse adverse event reports involve marijuana—far less than many other controlled substances, including substances in schedule V.)

[13] Letter from HHS to DEA, Basis for Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act (Aug. 29, 2023) at 64-65.

As a medical advisor to multiple organizations, including the Veteran's Cannabis Project, and as a governor-appointed member of the New Hampshire Therapeutic Medical Cannabis Oversight Board, Dr. Burchman offers valuable insight into the medical efficacy of cannabis and its potential for harm reduction. Dr. Burchman is well-positioned to provide expert testimony on the necessity of rescheduling cannabis under the Controlled Substances Act.

Dr. Alan Shackelford has trained and worked as an internal medicine, nutritional medicine, behavioral medicine, and occupational medicine physician and is also an expert on the risk potential of marijuana and on its therapeutic uses. Dr. Shackelford brings a wealth of knowledge on the medical efficacy and safety of marijuana. With extensive experience treating patients suffering from opioid dependence and conditions such as Parkinson's and inflammatory bowel disease, Dr. Shackelford advocates for marijuana as a safer and more effective treatment option. As a trained internist and researcher (at the University of Heidelberg in Germany and Harvard Medical School hospitals), his work has been hindered by marijuana's schedule I status, and he is prepared to provide critical insights on the importance of rescheduling to advance medical research and patient care.

Marijuana, like most drugs, can be "abused". But what constitutes "abuse" in the context of a culturally available and state-regulated substance cannot be based simply on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice, when no harm befalls the individual. A glass of wine with dinner, or the use of pain management medication, including Tylenol, in line with a doctor's recommendation, are not considered "abuse".[14] Likewise, occasional marijuana consumption per a doctor's recommendation, and use which presents no individual or societal harm is also not "abuse". The Proposed Rule recognizes that "the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others." None of that is "abuse", and in assessing prevalence as part of a potential abuse assessment, DEA should neither include medical uses of marijuana nor non-problematic non-medical uses. Relatedly, state-legal medical marijuana frameworks reduce marijuana's abuse potential due to strict labeling, packaging, testing, potency, and provider recommendation and guidance requirements. Sensible Colorado is well situated to provide evidence at the December 2, 2024, hearing to support this approach.

While the Proposed Rule would reschedule marijuana to schedule III, certain crucial consequences of this momentous decision remain unanswered. Sensible Colorado is well, and uniquely, positioned to present evidence addressing these unanswered questions. Sensible Colorado is a nonprofit organization with members that include many participants in Colorado's state-legal, regulated medical marijuana program. Colorado has one of the longest standing state and local regulated medical marijuana programs in the country. Sensible Colorado's members include researchers, healthcare providers, and veterans. The Proposed Rule will, once finalized, directly affect Sensible Colorado and its members. Among other things, "if marijuana is transferred into schedule III, DEA will continue to have authority to maintain its existing regulatory scheme . . . governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest

[14] States with medical marijuana programs require a doctor's recommendation to access the medical marijuana market, and doctor's recommendations outline the limits to a patient's access to marijuana and marijuana products, in terms of purchase limits. The use of marijuana in this manner is not abuse.

marijuana." Id. at 44,620; *see also id.* at 44,621 ("If marijuana is transferred to schedule III, the regulatory controls applicable to schedule III-controlled substances would apply, as appropriate."). In other words, Sensible Colorado and its members may be subject to additional controls pursuant to the CSA's regulatory authorities, as well as any other regulatory controls applicable to schedule III substances. OLC, Questions Related to the Potential Rescheduling of Marijuana, at 4 (Apr. 11, 2024). Accordingly, Sensible Colorado requests to participate in the hearing.

D. Sensible Colorado Meets the Requirements for Standing

Sensible Colorado has standing to participate in a hearing if one occurs. Sensible Colorado is an Interested Person and falls within the CSA's zone of interests. Further, Sensible Colorado and its members will be both directly adversely affected and aggrieved by the Proposed Rule, if finalized.

1.

The Proposed Rule is a "scheduling action" issued under 21 U.S.C. § 811(a). Id. at 44,598; id. at 44,621. The Administrative Procedure Act ("APA"), the CSA, and DEA regulations set out the governing standards for this scheduling action and related rulemaking proceedings. *See id.* at 44,598–99.

Under the APA, 5 U.S.C. § 555(b), "an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding," "[s]o far as the orderly conduct of public business permits." DEA regulations accordingly provide that an Interested Person may file a request to participate in a hearing. 21 C.F.R. § 1308.44(c). As the Proposed Rule was promulgated under 21 U.S.C. § 811(a), DEA's definition of Interested Person may apply here. *See* Proposed Rule at 44,598; id. at 44,621. We note that DEA has not formally defined "adversely affected or aggrieved" for purposes of the definition of an Interested Person." *See* In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, DEA Dkt. No. 22-15 (May 6, 2022) at 2 ("ALJ Order"). ALJs have correctly concluded that it is sufficient that a person falls within the CSA's "zone of interests" to be considered adversely affected or aggrieved. *See id.* at 5–6. As the discussion that follows demonstrates, Sensible Colorado qualifies as an Interested Person under either standard.

2.

Sensible Colorado is an Interested Person for two primary reasons.

First, Sensible Colorado falls within the CSA's "zone of interests." In May 2022, a DEA ALJ concluded that the test for "adversely affected or aggrieved"—and consequently, Interested Person—was satisfied when the person fell within the "zone of interests" to be regulated by the CSA. ALJ Order at 10. The Supreme Court of the United States has explained that the "zone of interests" test is "not meant to be especially demanding" given Congress' intent to "make agency action presumptively reviewable." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak,* 567 U.S. 209, 225 (2012) (citation omitted).

A party falls "within the zone of interests," the ALJ explained, "if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). Regarding the CSA, the Supreme Court has noted that the statute was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2005).

Sensible Colorado falls within the CSA's zone of interests. To start, Sensible Colorado and its members are regulated by the Proposed Rule and the CSA. Sensible Colorado and its members are actively involved in the state-legal marijuana industry. Each day, Sensible Colorado supports the state-regulated market for medical marijuana and medical marijuana products and actively fights against the perils of the illicit marketplace; and each day, its members purchase and use medical marijuana. And as we outline below, Sensible Colorado and its members may see new marijuana-specific controls related to marijuana-related activities under the Proposed Rule. Proposed Rule at 44,620–21.

In light of the foregoing, Sensible Colorado satisfies both standing tests reviewed in *Students for Fair Admissions*. Under the first test, an organization may demonstrate standing by showing that it is injured in its own right. 600 U.S. at 199. As described throughout this request, Sensible Colorado has suffered a concrete injury itself as a result of the Proposed Rule. Among other things, Sensible Colorado spends time, money, and other resources to advocate for a regulated, responsible medical marijuana marketplace, and the Proposed Rule imperils these expenditures.

Under the second test, associational standing is demonstrated when an organization can show "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* (quoting *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977)). Sensible Colorado meets each of these elements. As discussed herein, Dr. Corey Burchman, Dr. Alan Shackelford, Todd Young, Daniel Molina, Anonymous, Anonymous #2, and Anonymous #3, among other Sensible Colorado members, have standing to participate, which, in turn, confers standing upon Sensible Colorado. The interests Sensible Colorado seeks to protect are germane to the organization's purpose: to foster a viable, safe, and regulated medical marijuana market with particular attention to public health and safety and consumer protection. Sensible Colorado can serve as a representative of its members in this proceeding, and the participation of individual members is not required.

Additionally, Sensible Colorado, satisfies the APA's standard to sue DEA in federal district court in relation to the Proposed Rule; 5 U.S.C. § 551 et seq., authorizes suit to challenge a federal agency by any "person ... adversely affected or aggrieved . . . within the meaning of a relevant statute." § 702. The Supreme Court has held that this language establishes a regime under which a plaintiff may not sue unless he "falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 883 (1990). The Supreme Court has described the "zone of interests" test as denying a right of review "if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that

Congress intended to permit the suit." *Clarke v. Securities Industry Assn.*, 479 U.S. 388, 399–400 (1987). For the reasons explained herein, Sensible Colorado meets this standard and falls within the zone of interests of the CSA and the Proposed Rule.

Second, Sensible Colorado and its members would be adversely affected or aggrieved by the Proposed Rule, if finalized. Sensible Colorado and its members are prepared to present evidence on these facts at the hearing:

- **Medical research involving marijuana, particularly as it relates to veterans' access:** Research on marijuana's medical efficacy has been difficult to conduct because of marijuana's status as a schedule III substance. While this impacts all medical marijuana patients, it has particularly affected veterans' access to medical marijuana. Nonetheless, the research that has been done supports the conclusion that marijuana should be removed from schedule I of the CSA. Sensible Colorado, through Dr. Corey Burchman and/or Dr. Alan Shackelford, is well prepared to present expert witness evidence of this at DEA's December 2, 2024, hearing.

- **Marijuana's medical efficacy:** Many states, including Colorado, have decades old medical marijuana programs which recognize marijuana's medical use in treatment for numerous conditions, including chronic pain. Public health has substantially benefitted from marijuana's availability as part of medical treatment regimes. Sensible Colorado is uniquely situated to provide expert witness evidence of this. Sensible Colorado Members, including Dr. Corey Burchman and/or Dr. Alan Shackelford, is well prepared to present expert witness evidence of this at DEA's December 2, 2024, hearing.

- **The effects of the Proposed Rule on members of Sensible Colorado who are minority owned-owned/small businesses and on members whose communities have been impacted by the war on drugs:** Anonymous #3 is a privately owned business operating within the state-legal medical and adult use Colorado marijuana programs. It started providing medical marijuana to Colorado patients in 2010 and continues to do so today. With the burden of 280E strangling the industry, if DEA fails to move marijuana outside of schedules I and II, Anonymous #3, along with many other responsible and regulated companies may have to shut down their operations. The inapplicability of 280E would also allow Anonymous #3 to better compete with the illicit market, further deteriorating its influence on the market. Owners of Anonymous #3 are prepared to present written expert testimony on the extreme burden 280E places on small business such as themselves and how the removal of that burden will not only allow the company to continue operating but also provide a benefit to the communities in which Anonymous #3 operates.

  Todd Young, a disabled medical marijuana patient, has been severely impacted by marijuana's schedule I status. After breaking his back, he credits medical marijuana with saving his life, allowing him to avoid far more dangerous substances. Despite possessing a valid medical marijuana license, he has faced arrest, financial hardship, and family separation. Living on the Mohawk Nation's reservation to grow enough marijuana for his

medical needs, Todd is a powerful advocate for descheduling, which would allow him to reunite with his family and grow his medicine without fear of legal consequences.

Daniel Molina, a veteran of the Global War on Terror and a disabled U.S. Army Combat Medic, has been deeply affected by marijuana's schedule I status. After serving overseas for over two and half years, Molina returned home with multiple disabling conditions and a 90% VA disability rating. He found that medical marijuana was the most effective treatment for his symptoms but was forced to relocate from Texas to Colorado to access it legally. Now a third-year law student and law clerk at Vicente LLP, Molina advocates for veterans' rights and highlights the life-saving potential of medical marijuana for those suffering from service-related disabilities.

Anonymous, a longstanding medical marijuana patient over the age of 60, relies solely on cannabis to manage the symptoms of a rare form of muscular dystrophy. Due to fear of arrest, this individual remains anonymous, but their story highlights the severe limitations imposed by marijuana's schedule I status. Despite the relief provided by medical marijuana, they have been forced to rely on the illicit market and live in constant fear of losing access to this vital treatment. Their testimony underscores the urgent need for rescheduling to protect patient rights and improve access to life-saving medicine.

Anonymous #2, a medical marijuana patient diagnosed with Complex PTSD, has faced significant professional and personal hardships due to marijuana's schedule I status. Despite being qualified and headhunted for positions, they have been denied employment, including at RTD Denver, because of their medical marijuana use. This individual also experiences fear while traveling and is separated from family in states where medical marijuana is not recognized. Their story highlights the pervasive stigma and discrimination faced by patients and underscores the need for rescheduling to protect patient rights and improve societal understanding.

- **The abuse potential, public health risks, and illicit market for Marijuana:** The public health risks of marijuana are far less significant than fentanyl, cocaine, or other controlled substances in schedule II. Further, marijuana poses less public health risks than substances in schedules III, IV, and V; this includes benzodiazepines (controlled in schedule IV of the CSA), antipsychotics (control varies; in the case of risperidone and aripiprazole, uncontrolled), and cough medicines containing codeine (controlled in schedule V of the CSA). Sensible Colorado is prepared to present expert testimony on marijuana's abuse potential, currently accepted medical use in treatment in the United States, and the placement of marijuana on the CSA's schedules. Dr. Alan Shackelford, a member and advisor to Sensible Colorado, is prepared to testify about the abuse potential of marijuana compared to other controlled substances.

- **Marijuana's usefulness in replacing other more harmful substances (i.e. alcohol and opioids):** As the opioid crisis continues to plague our country, and as the long-term effects of substances like alcohol and benzodiazapines become more and more clear, marijuana is a useful tool in treating multiple public health crisis's. Marijuana is particularly useful as a substitute for other more harmful substances, and it has value for those wishing to reduce

their consumption of other more harmful substances. Sensible Colorado has members, including Todd Young and Daniel Molina, who are well prepared to present factual testimony of this; and Sensible Colorado is well prepared to present expert witness testimony of this.

- **Todd Young, Anonymous, and Anonymous #2, among other members of Sensible Colorado, have had to live with the risk, and the psychological impacts of the risk, of arrest and prosecution for personal possession of state-legal medical marijuana.** This is a risk that all patients under state-legal medical marijuana programs currently face. These members are prepared to present testimony to this effect.

- **The practical consequences of rescheduling marijuana:** DOJ acknowledges that it is seeking comments on the "practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks." Proposed Rule at 44,621. Sensible Colorado is prepared to provide expert testimony and documentary evidence on the practical consequences of rescheduling across the marijuana supply chain, from seed to sale.

Concurrent with this rulemaking, the agency is considering marijuana-specific controls associated with international treaty obligations. Proposed Rule at 44,599. The Office of Legal Counsel ("OLC") concluded that "additional controls pursuant to the CSA's regulatory authorities" may be necessary. OLC, Questions Related to the Potential Rescheduling of Marijuana, at 4 (Apr. 11, 2024). New DEA controls would adversely impact how Sensible Colorado's members access medical marijuana and would impose new costs. Without knowing what the new regulations will be, current state-legal medical marijuana patients face the risk that forthcoming regulations will make their respective state programs subject to increased enforcement action from DEA. This is especially concerning given that state-legal medical marijuana programs can't rely on Congress to reapprove the rider which prohibits the federal government from spending funds to police state-legal medical marijuana programs.[15]

Sensible Colorado has members like Todd Young, Daniel Molina, Anonymous, and Anonymous #2, who utilize the state-legal medical marijuana program, in particular. Despite the millions of patients and tens of thousands of licensed healthcare professionals using and recommending medical marijuana products in treatment across the country, the federal government had, until this administrative process, repeatedly insisted that marijuana had no currently accepted medical use in treatment in the United States.

Accordingly, Sensible Colorado submits this filing to participate to the fullest extent permissible by law in this rulemaking hearing. Sensible Colorado is an Interested Person because the Proposed Rule would adversely affect and aggrieve Sensible Colorado and its members.

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[15]"In each budget cycle since FY2014, Congress has passed an appropriations rider barring the Department of Justice (DOJ) from using taxpayer funds to prevent states from 'implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.'" *Legal Consequences of Rescheduling Marijuana*, Congressional Research Service (May 1, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11105#:~:text=In%20each%20budget%20cycle%20since,marijuana.%E2%80%9D%20Courts%20have%20interpreted%20the.

Put simply, the Proposed Rule, if finalized, would directly and adversely affect Sensible Colorado and its members. Sensible Colorado needs to show only administrative standing, rather than Article III standing, to participate in this administrative proceeding. *Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (discussing a lower threshold required for "administrative standing" compared to Article III standing). However, for all the reasons just described, Sensible Colorado meets the requirements of both standards. Broad participation in agency proceedings and an expansive understanding of the term "Interested Person" are often necessary because the agency's decision-making implicates public policy. Id.

E. No Basis Exists to Deny Sensible Colorado's Participation in the Hearing

Sensible Colorado represents medical marijuana patients in Colorado that are directly and adversely affected by the Proposed Rule. Sensible Colorado is thus uniquely situated to assist DEA's administrative decision-making. Sensible Colorado has extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated medical marijuana marketplace. DEA has sought comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. Sensible Colorado is particularly well situated to provide this insight.

No basis exists to deny Sensible Colorado's participation if DEA convenes a hearing. In fact, none of the reasons which courts have cited to deny a movant's participation in an administrative proceeding apply here. *See Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). Collecting cases, the D.C. Circuit noted that courts had denied participation when (i) other parties to the proceeding adequately represent the would-be participant's viewpoint; (ii) participation would unduly broaden the issues considered or obstruct or overburden the proceedings; or (iii) participation would fail to assist the agency's decision-making. Id.

First, no other participant in the rulemaking would adequately represent Sensible Colorado's viewpoint.[16] Sensible Colorado has interests in the rulemaking proceedings distinct from those of DEA. Sensible Colorado represents an important and diverse group of interests that can speak to marijuana's medical efficacy, the abuse potential and public health risks of marijuana, and marijuana's potential for replacing the use of other more harmful substances (i.e. alcohol and opioids), among other topics.

Second, Sensible Colorado's participation would not unreasonably broaden the issues under consideration in the Proposed Rule or obstruct proceedings. DEA has sought information on the practical consequences of rescheduling. Sensible Colorado is prepared to provide that perspective at the hearing. Sensible Colorado would abide by requirements and briefing standards applicable to other participants in the formal rulemaking procedure.

Third, Sensible Colorado's participation would benefit the agency's decision-making process. As noted above, Sensible Colorado's unique perspective would provide insight into: (i) medical and

[16] While this filing is made without knowledge of other participants in the potential ALJ hearing, Sensible Colorado provides a unique perspective that would not be cumulative to or adequately represented by other participants if DEA grants a hearing on the Proposed Rule.

scientific research involving marijuana, including as it relates to veterans' access; (ii) marijuana's medical efficacy, including the use of marijuana in the practice of medicine in the U.S. under state-legal programs (particularly in Colorado); (iii) the effects of the Proposed Rule on members of Sensible Colorado who are minority-owned/small businesses and on members whose communities have been impacted by the war on drugs ; ; (iv) the abuse potential, public health risks, and illicit market for marijuana; (v) marijuana's usefulness in replacing other more harmful substances (i.e. alcohol and opioids); (vi) the specific ways Sensible Colorado's members will be adversely affected and aggrieved by the Proposed Rule, if finalized; and (vii) the practical consequences of rescheduling marijuana. Sensible Colorado is prepared to present expert testimony on these issues.

For all these reasons Sensible Colorado hereby requests the ability to participate in the rulemaking process to the fullest extent permissible by law and participate in the December 2, 2024, hearing.

All notices and correspondence to be sent pursuant to this appearance should be addressed to me at the address provided below.

Respectfully yours,

/s/ Timothy D. Swain
Timothy D. Swain
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Enclosures:

- Exhibit A: Declaration of Dr. Corey Burchman
- Exhibit B: Declaration of Dr. Alan Shackelford
- Exhibit C: Declaration of Todd Young
- Exhibit D: Declaration of Daniel Molina
- Exhibit E: Declaration of Anonymous
- Exhibit F: Declaration of Anonymous #2
- Exhibit G: Declaration of Anonymous #3

EXHIBIT A
Declaration of
Dr. Corey Burchman

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

EXPERT WITNESS DECLARATION OF DR. COREY BURCHMAN

EXPERT WITNESS DECLARATION OF DR. COREY BURCHMAN

I, Dr. Corey Burchman declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently testify to the matters stated herein.

2. I am a neuro-anesthesiologist and obstetrical anesthesiologist, and a former U.S. Navy physician.

3. I am a member of the Coalition for Cannabis Scheduling Reform, a medical advisor to the Veteran's Cannabis Project, and a board member of Hemp for Victory. I am also a governor-appointed member of the New Hampshire Department of State Therapeutic Medical Cannabis Oversight Board, and I am an active medical professor at the Geisel School of Medicine at Dartmouth.

4. In the context of Point 3, in my role as a medical advisor to the Coalition for Cannabis Scheduling Reform, I offer learned opinions on the subject of harm reduction, addiction potential, and rescheduling as it pertains to federal marijuana policy.

5. I will provide relevant information on marijuana's benefit as a replacement for various controlled substances and information supporting marijuana's medical efficacy and its lower abuse potential relative to other substances controlled under the Controlled Substances Act.

6. No other party to these proceedings will adequately represent my viewpoints.

7. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 28, 2024.

Dr. Corey Burchman
CBurchman@gmail.com

EXHIBIT B
Declaration of
Dr. Alan Shackelford

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

EXPERT WITNESS DECLARATION OF ALAN SHACKELFORD, M.D.

EXPERT WITNESS DECLARATION OF DR. ALAN SHACKELFORD

I, Dr. Alan Shackelford, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently testify to the matters stated herein.

2. I have trained and worked as an internal medicine, nutritional medicine, behavioral medicine and occupational medicine physician and I am an expert on the risk potential of marijuana and on its therapeutic uses.

3. I have worked extensively with opioids in the past and have seen the value that marijuana provides my patients. Marijuana is a safer and more effective means of treatment than opioids for many patients.

4. I have also seen the benefit that marijuana provides in the treatment of various diseases such as Parkinson's disease and inflammatory bowel disease.

5. I trained at the University of Heidelberg in Germany and at Harvard Medical School hospitals in the United States. I am a Harvard Medical School-trained internist and researcher and co-authored a number of research papers at both universities. My research on marijuana's efficacy and abuse potential has been severely impacted and limited due to marijuana's status as a Schedule I substance, particularly as it relates to the cost of conducting research on marijuana in the United States.

6. I have been stigmatized by colleagues and by professional institutions for my interest in the use of marijuana as a medical treatment and in properly studying those uses.

7. I first encountered patients using marijuana for medical purposes circa 2008-2009. In 2012, I authorized the use of a specific medical marijuana extract by Charlotte Figi, a five-year-old suffering 300 grand-mal seizures a week. Despite its success in stopping the seizures, I had to answer to the medical director of the Colorado Department of Public Health and was in fear of losing my medical license and ability to make a living.

8. Based on my 15 years of experience, if marijuana were rescheduled or descheduled, I would prescribe it as a highly effective treatment for numerous conditions and diseases.

9. I will provide relevant information on marijuana's medical efficacy and minimal relative abuse potential, as well as the impact that rescheduling or descheduling would have on the costs and extreme difficulties associated with conducting research on marijuana.

10. No other party to these proceedings will adequately represent my viewpoints.

11. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 30, 2024.

Alan Shackelford, M.D.

Arzt84@yahoo.com

EXHIBIT C
Declaration of
Todd Young

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

FACTUAL WITNESS DECLARATION OF TODD YOUNG

EXPERT WITNESS DECLARATION OF TODD YOUNG

I, Todd Young, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently testify to the matters stated herein.

2. I am a disabled medical marijuana patient who has been severely impacted by marijuana's status as a schedule I substance.

3. I have been harmed by my inability to travel between states with my personal supply of medical marijuana and by not being able to cultivate marijuana plants in a high enough number to meet my own medical needs.

4. I broke my back many years ago, and if it were not for medical marijuana, I'm certain that I would have died many years ago due to complications from much more dangerous substances.

5. I need to consume medical marijuana in a concentrated form to effectively treat my condition, and I am not allowed to personally extract my own concentrate from my marijuana plants; this has caused me significant financial harm because I have had to buy these products at inflated prices.

6. I was arrested in Jefferson County, Colorado many years ago for possession of marijuana, despite having a valid medical marijuana license.

7. My children have faced hazing and inappropriate behavior from schoolmates because of my appearance in the media related to my marijuana use; and I have lived in fear of losing my children to the state due to this.

8. I currently live on the Mohawk Nation's reservation in order to grow the amount of marijuana that I need to survive. Because of this I am separated from my family and am only rarely able to travel to see them.

9. Because of the proximity of the Mohawk Nation to the Canadian border, I have encountered U.S. border patrol when leaving the reservation, and they have taken my medical marijuana from me on multiple occasions.

10. If marijuana were descheduled, I would be able to leave the reservation and rejoin my family; I would be able to grow a sufficient amount of plants to treat my condition without fear of persecution and incarceration.

11. I will provide relevant information on marijuana's value to me as a disabled individual, and I will explain how descheduling marijuana will positively impact my life, the lives of my family members, and the lives of those that are in similar circumstances to my family and I.

12. No other party to these proceedings will adequately represent my viewpoints.

13. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 27, 2024.

Todd Young

Todd Young
Pabilsag02@gmail.com

EXHIBIT D
Declaration of
Daniel Molina

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

FACTUAL WITNESS DECLARATION OF DANIEL MOLINA

EXPERT WITNESS DECLARATION OF DANIEL MOLINA

I, Daniel Molina, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently testify to the matters stated herein.

2. I am a disabled U.S. Army Combat Medic veteran of the Global War on Terror. I served at a level 1 trauma center where I treated casualties from both the wars in Iraq and Afghanistan before serving as a combat medic in Afghanistan in the 101st Airborne Division, 2nd Battalion, 327th Infantry Regiment, from 2012 to 2013.

3. I left the Army with an Honorable Discharge in December of 2013 after completing two terms of service.

4. I now suffer from over a half dozen diagnosed disabling conditions, and I have a combined Department of Veterans Affairs ("VA") disability rating of 90%.

5. The VA prescribed me numerous prescription medications after I left the service, and I suffered from the side effects of those medications. As a result I started researching adequate alternatives to help meet my day-to-day needs related to my disabilities. I ultimately discovered that marijuana, in various forms, was effective at treating the vast majority of the symptoms associated with my disabilities.

6. In 2015, about 2 years after leaving the service, I was living in Texas, and I was in great fear that I could be reported by my neighbors for using marijuana, in my apartment, to help treat my symptoms. At the time my apartment was the only place I felt comfortable using marijuana, after receiving a citation for being in possession of marijuana paraphernalia at a state park.

7. I determined that relocating to Colorado to become a registered medical marijuana patient was paramount to improving my health and to avoid being arrested for using marijuana.

8. At the time, I was a student at Austin Community College ("ACC") and I was working for a state representative at the Texas Capital. I had hoped to transfer

from ACC to the University of Texas and to continue my work at the state legislature, but it was clear that by staying in Texas, where no medical marijuana program existed, I was risking my educational and professional future.

9. In May of 2015, I moved to Colorado, enrolled in the medical marijuana program, and enrolled at the University of Colorado at Colorado Springs ("UCCS").

10. After graduating from my undergraduate program at UCCS in 2018, I started considering graduate programs in Texas due to the new Texas Compassionate Use Program. However, that program was wholly inadequate for my medical needs and I decided to enroll in a graduate program at UCCS.

11. Similarly, prior to attaining my graduate degree in 2022, I applied to law school programs in several states, including Texas and Colorado. I was granted a full-ride scholarship to Texas Southern University's law program, and a substantial scholarship to the University of Houston's program, where Texas' Hazelwood Act would have paid the remainder of my tuition.

12. However, the political and regulatory climate in Texas had still not moved in a direction where I would have felt safe in Texas as someone who used marijuana for medicinal purposes. I decided to stay in Colorado and attend the University of Denver's law program, where I had been accepted. I have now had to take out over $100,000.00 in student loans to pay for my law degree, which is still in progress.

13. I am now in my third year of law school and I work as a law clerk at Vicente LLP, where I can contribute to the evolving landscape for marijuana in the states and at the federal level.

14. I have been substantially impacted by marijuana's status as a schedule I substance under the Controlled Substances Act.

15. I will provide relevant information on the (1) harm to veterans attributable to marijuana's status as a schedule I substance; (2) marijuana's usefulness in treating a half dozen disabilities, which I sustained as a result of my

service to the United States of America; and (3) the deaths of fellow service members which could have been mitigated had they had access to adequate medical marijuana as a substitute to prescription drugs.

16. No other party to these proceedings will adequately represent my viewpoints.

17. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 27, 2024.

Daniel Molina

Daniel Molina
Danielmolina1236@gmail.com

EXHIBIT E
Declaration of
Anonymous

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

FACTUAL WITNESS DECLARATION OF ANONYMOUS

EXPERT WITNESS DECLARATION OF ANONYMOUS

I, ANONYMOUS, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently submit written testimony to the matters stated herein.

2. I am a longstanding medical marijuana patient over the age of 60.

3. I desire to remain anonymous because I live in constant fear that my medical use of marijuana will lead to my arrest. If I am incarcerated, I would have no access to an adequate alternative to medical marijuana, and I would suffer immensely.

4. In 2003 I was diagnosed with a rare form of muscular dystrophy, for which there is no prescription medication that will treat my symptoms. Medical marijuana is the only substance that provides me with the relief that allows me to live a productive life.

5. I have been forced to purchase marijuana on the illicit market due to the low availability and legality from the time I was diagnosed with my disease.

6. I cannot travel freely because of my fear that I will be caught with my medical marijuana.

7. In addition to being a medical marijuana patient, I have been a medical marijuana caregiver. In 2007, when the DEA tried to force the state of Colorado to limit extended plant counts, my patients and I were terrified that this would negatively impact our lives.

8. The relationship between my doctor and I should be completely private, and the federal government is trespassing on doctor/patient relationships and privileges by continuing to list marijuana as a schedule I substance.

9. The fact that I am in such fear that I cannot reveal my identity for the purposes of this hearing is dehumanizing and it is a real and tangible injury.

10. I will provide relevant written testimony on the value that medical marijuana has to me and to others like me. I will also provide further information on how marijuana's status as a schedule I substance has negatively impacted my life and the ways in which my life will be improved if marijuana is either rescheduled or descheduled.

11. No other party to these proceedings will adequately represent my viewpoints.

12. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 27, 2024.

//A//
ANONYNOUS

EXHIBIT E
Declaration of
Anonymous 2

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

FACTUAL WITNESS DECLARATION OF ANONYMOUS #2

EXPERT WITNESS DECLARATION OF ANONYMOUS #2

I, ANONYMOUS #2, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, provide written testimony to the matters stated herein.

2. I am a medical marijuana patient and have worked for marijuana businesses; and I have been severely harmed by marijuana's status as a schedule I substance because of both of those statuses.

3. I qualify as a medical marijuana patient due to my diagnosis of Complex PTSD.

4. I have been denied employment by RTD Denver, government agency, after having been headhunted, signing an employment agreement, and after completing a weeks-long onboarding process because of my status as a medical marijuana patient. The onboarding process occurred subsequent to my disclosure of my status as a medical marijuana patient and subsequent to lengthy discussions with the employer about the skills I have gained while working for marijuana businesses. Because of this, I lost an opportunity for a substantial increase in salary.

5. I have received a letter from a potential employer, after having disclosed my status as a medical marijuana patient, that served as a referral notice to a substance abuse counselor. It stated that I either had a verified positive test result or refused the test and that resulted in immediate removal from my position. It concluded that if I were to apply to RTD again in the future, I'd need to provide evidence that I completed a rehabilitation program and followed the

recommendations of a substance abuse counselor. This was dehumanizing; I am a registered patient and I do not abuse my medication.

6. I endure fear while traveling, because if I am in a state where my status as a medical marijuana patient is not recognized, I will not be able to adequately treat myself when I exhibit symptoms from my PTSD.

7. The majority of my family lives in Texas and I am unable to work there due to fear of prosecution; because of this, I am separated from my loved ones on a regular basis.

8. I will provide relevant information on the personal and societal harms caused by marijuana's status as a schedule I substance, and I will explain the value that rescheduling, or descheduling, will have for medical marijuana patients like myself.

9. No other party to these proceedings will adequately represent my viewpoints.

10. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 27, 2024.

//A//
ANONYMOUS #2

EXHIBIT E
Declaration of
Anonymous 3

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, VA 22152

In the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597

Docket No. DEA-1362

Currently scheduled for December 2, 2024, at 9:00am E.T.

FACTUAL WITNESS DECLARATION OF ANONYMOUS #3

EXPERT WITNESS DECLARATION OF ANONYMOUS #3

I, declare as follows:

1. I have personal knowledge of the facts set forth herein, and if called as a witness, I can, and will, competently provide written testimony to the matters stated herein.

2. I am co-owner of Anonymous #3.

3. Anonymous #3 is a privately owned business operating within the state-legal medical and adult-use Colorado marijuana programs. The company started providing medical marijuana to patients in 2010, and it continues to do so today.

4. Anonymous #3 is subject to the restrictions of 26 U.S.C. § 280E ("280E"). As such, the immense tax burdens on the company may force the company to shut down its operations; this would impact a large number of employees and consultants who rely on the company financially.

5. I will provide relevant information on the impacts of 280E on state-legal marijuana businesses and the ability of these businesses to outcompete the illicit market if marijuana is scheduled outside of schedules I and II.

6. No other party to these proceedings will adequately represent my viewpoints.

7. My participation will not unduly broaden the issues considered or obstruct or overburden the proceedings.

I declare that the foregoing is true and correct.

Executed September 27, 2024.

//A//
Anonymous #3

September 30, 2024

Subject: Docket No. DEA-1362, Request for Participation

Dr. Sue Sisley and Scottsdale Research Institute ("SRI") request to participate in the hearing in the matter of Schedules of Controlled Substances: Rescheduling of Marijuana, Docket No. DEA-1362.

1. **Interests.**

Dr. Sisley and SRI are registrants that hold Schedule I licenses to manufacture and research marijuana. Dr. Sisley and SRI support descheduling, or in the alternative, rescheduling marijuana. As Schedule I registrants actively engaged in researching marijuana, including FDA clinical trials, they are interested in the rule and request the opportunity to provide Dr. Sisley's testimony to DEA at the rulemaking hearing to offer a unique and nuanced perspective on the issues.

As registrants actively engaged in research, Dr. Sisley and SRI have an interest in rescheduling. Several regulatory requirements applicable to schedule I and II substances are stricter than those applicable to substances in schedule III, such as inventory requirements (21 C.F.R. § 1304.11(e)(6)), export requirements (21 C.F.R. § 1304.11(e)(6)), orders (21 C.F.R. § 1305.04, .21), and drug storage requirements. The notice of proposed rulemaking expressly acknowledges that "small entities engaged in research on marijuana" such as SRI "may be subject to different research protocols set by DEA if the research is conducted on a schedule III substance rather than a schedule I substance." Thus, they are interested in rescheduling insofar as it may remove current restrictions on research.

Although, Dr. Sisley and SRI believe that rescheduling's impact would alleviate some of the above burdens, they also believe that impact on research is overstated. In their experience, over the past several years, marijuana's Schedule I status has not meaningfully impeded scientific and medical research and that factors unrelated to marijuana's current schedule present more difficulties. Dr. Sisley and SRI are interested in making that point of view part of the rulemaking record.

Dr. Sisley is also a widely recognized expert and public speaker in marijuana research and clinical marijuana science and has an interest in providing expert testimony at the hearing. In particular she will put certain marijuana studies discussed or cited in the HHS evaluation into context and relate the experience of veterans she's worked with and patients she's observed. In particular, the HHS report specifically discusses a randomized control trial conducted by Dr. Sisley and SRI to treat PTSD. As an active practitioner and researcher, Dr. Sisley offers a unique perspective on whether there is an accepted safety for use of marijuana under medical supervision.

2. **Objections/issues.**

Sisley and SRI with to be heard on any of the following issues.

a. Whether and to what extent DEA must impose additional regulatory restrictions beyond schedule III to ensure treaty compliance, and if so, what those restrictions should be.
b. Whether DEA can deschedule marijuana.
c. Whether and to what extent rescheduling will improve research, and whether and to what extent marijuana's current schedule I status in fact impairs research.
d. Whether marijuana's abuse potential and risks of use are less than those of substances in schedules III or IV.

3. **Brief Statement on Issues.**

Dr. Sisley and SRI believe that rescheduling would alleviate certain research burdens, but that today, the most significant research burdens relate to regulatory requirements outside of the CSA. In particular, current difficulties with marijuana research, particularly clinical research, relates to funding issues and FDA regulatory requirements, not CSA regulatory requirements. As a result, rescheduling will not improve marijuana research to the extent some have claimed.

September 30, 2024

Dr. Sisley and SRI believe many regulatory restrictions currently imposed by DEA to ensure treaty requirements are unnecessary if marijuana is rescheduled to schedule III and can be eliminated, and that descheduling is possible.

Dr. Sisley and SRI believe that marijuana's abuse potential, particularly when used medically, is less than the abuse potential and risks of use are less than those of many substances in schedules III or IV.

Notices to be sent pursuant to the proceeding should be addressed to:

Scottsdale Research Institute, LLC
12622 N. 81st St., Scottsdale AZ 85260
Att'n: Dr. Suzanne Sisley
ssisleymd@gmail.com
(480) 326-6023

Respectfully yours,

Suzanne Sisley, MD
Scottsdale Research Institute, LLC

JARED POLIS
GOVERNOR

136 STATE CAPITOL
DENVER, COLORADO 80203

TEL 303-866-2471
FAX 303-866-2003

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Notice of Appearance (Docket No. DEA-1362)

Dear Administrator Milgram,

The State of Colorado requests to appear in the matter of The Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule") currently scheduled to take place on December 2, 2024.

(A) The State of Colorado has standing to participate in this administrative hearing as an "interested person" defined under 21 CFR 1300.01(b). The State is requesting the below listed parties participate at the hearing to offer distinct factual evidence and expert opinion regarding the rescheduling of marijuana. The State's status as an "interested person" as defined in §1300.01, and the status of the representatives requesting to participate in the hearing on behalf of Colorado, are detailed further below.

The State's public officials who have a role in administering, overseeing and advising on the success of Colorado's marijuana framework, as well as the people of Colorado, will be adversely affected or otherwise aggrieved by the Proposed Rule if marijuana remains a Schedule I Controlled Substance.

Colorado's legal marijuana industry has generated over $16.3 Billion in sales over the past 10 years and has generated over $2.7 Billion in state tax and fee revenue. This industry has contributed to well over 40,000 jobs of just those directly involved in the industry, in addition to the tens of thousands of professionals in ancillary industries who support the marijuana industry. As this sector continues to grow at a rapid pace, the State is concerned that a federal rescheduling determination that lacks important insights and subject matter expertise from Colorado officials will introduce significant risks to the State's marijuana framework, the ability to continue to effectively carry out regulatory and policy responsibilities on behalf of the State, and the programs that marijuana tax revenue has funded to support communities across Colorado.

(B) Colorado possesses a cadre of subject matter experts who can provide unique insight related to medical marijuana. The State has had a robust medical program for 24+ years with licensed healthcare professionals and providers making recommendations to treat symptoms related to Autism, Cachexia, Cancer, Glaucoma, HIV/AIDS, Muscle Spasms, PTSD, Seizures, Severe Nausea and Chronic/Severe pain and as an option to avoid using opioids. The State leads a strong medical program with over 63,000 current registered medical marijuana patients including over 22,400 patients who have the qualifying condition of anything for which an opioid may be

prescribed. Given the country's opioid epidemic, our evidence of marijuana having medical utility and abuse potential far below opioids would inform DEA's process.

Our data is relevant, unique and, non-duplicative of any other state and our experts are well suited to inform the administrative process as the DEA considers the rescheduling of marijuana under the Controlled Substances Act.

The DEA's notice of rulemaking directly referenced Colorado data that our experts are prepared to address. Specifically, the notice of proposed rulemaking reference of public health risks associated with driving under the influence of marijuana, cited traffic deaths in Colorado. The data cited in the notice lacks important context that must be considered in this rulemaking. The public officials listed herein as interested parties are prepared to provide the context and additional data on traffic safety necessary to inform the rescheduling determination.

In addition, the State has robust data on youth use, which is directly relevant to DEA's analysis regarding abuse potential. Notably, the questions we ask in our Healthy Kids Colorado Survey has more specific survey questions related to use and perceptions of use than SAMSHA's National Survey on Drug Use and Health and CDC's Youth Risk Behavior Surveillance System. Importantly, our data will show that youth use has not increased post legalization. Colorado youth continue to use marijuana at lower rates than their peers nationally. While we acknowledge harms associated with illicit use, the overwhelming conclusions demonstrate that the legalization of marijuana in our state is contributing to decreased youth use, not the opposite.

(C) Our public officials have significant subject matter expertise regulating the medical and adult-use markets over the past decade and are prepared to testify regarding data attributable to medical use in treatment in the United States and relative abuse potential of marijuana. Our State is particularly well situated to provide this insight as we are one of the first states to legalize and regulate medical marijuana and the first to legalize adult-use.

For more than 10 years, our Senior Director of Enforcement at the Marijuana Enforcement Division (MED), Dominique Mendiola, has served as a regulator for the MED. Mendiola is also the current President of the Cannabis Regulators Association (CANNRA), a national association of agencies responsible for regulating cannabis and cannabinoids. She has a perspective that is relevant and distinct from other state regulators. Other states have and continue to look at Colorado as a role model for what their state can do to protect public health. A federal rescheduling consideration that lacks clear guidance on how priorities and roles will change presents uncertainties and risks that can compromise the diligent efforts she and her MED team have made on behalf of the State.

Ean Seeb is our Governor's Special Advisor on Cannabis and Natural Medicine. He brings unique insights having been both an early industry operator in Medical and Adult-Use marijuana and has been part of our senior policy team for over half a decade, during which time the State has evolved on dozens of marijuana laws and regulations. As an advisor and partner to agencies charged with administering the State's marijuana program, a federal rescheduling consideration that references incomplete Colorado data and that lacks clear guidance on how priorities and roles will change under a proposed rescheduling presents similar uncertainties that will impact Seeb's ability to most effectively carry out his role on behalf of the State.

For the above reasons, the State of Colorado is filing this written request to have the parties referenced above participate at the upcoming Administrative Law Hearing scheduled December, 2nd, 2024. This notice of intention to participate conforms with 21 CFR 1308.44(b), by describing (a) the identity and interests of the parties who will participate in the hearing on behalf of the State of Colorado; (b) the details of the objections and issues concerning the matters to be heard; and (c) the positions of the parties regarding their objections and issues they are prepared to speak about in the hearing.

I look forward to your response, which I'm confident will align with the DOJ's commitment to conducting a transparent, balanced, and well-informed proceeding.

Respectfully,

Jared Polis
Governor
State of Colorado

All notices to be sent pursuant to this hearing should be addressed to the addresses listed below:

Governor Jared Polis
Colorado State Capitol
200 East Colfax Avenue, Room 136
Denver, CO. 80203
governorpolis@state.co.us

Ean Seeb
Colorado State Capitol
200 East Colfax Avenue, Room 127
Denver, CO. 80203
ean.seeb@state.co.us

Dominique Mendiola
1697 Cole Boulevard, #200
Lakewood, CO. 80401
dominique.mendiola@state.co.us

STATE OF NEBRASKA
Office of the Attorney General
2115 STATE CAPITOL BUILDING
LINCOLN, NE 68509-8920
(402) 471-2682
TDD (402) 471-2682
FAX (402) 471-3297 or (402) 471-4725

MIKE HILGERS
ATTORNEY GENERAL

September 30, 2024

Hon. Anne Milgram
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

Submitted via email (nprm@dea.gov)

Re: Notice of Intention to Participate in Hearing on the Proposed Rescheduling of Marijuana, Docket No. DEA–1362

Dear Administrator Milgram:

The State of Nebraska files this notice of intention to participate in the upcoming hearing regarding the proposed rescheduling of marijuana from Schedule I of the Controlled Substance Act (CSA) to Schedule III. *See* 89 Fed. Reg. 70149 (Aug. 29, 2024); *see also* 89 Fed. Reg. 44597 (May 21, 2024). As noted in the Nebraska-led comment on behalf of an 11-State coalition, the "harm inflicted by rescheduling will be especially acute in States like Nebraska, where state law makes marijuana illegal in all circumstances." Comment of States of Nebraska et. al. (July 22, 2024), available at https://perma.cc/PRE9-3FLL ("Nebraska Comment"). That harm means Nebraska is "adversely affected or aggrieved by . . . [the] proposed rule." 21 C.F.R. §1300.01(b). Accordingly, Nebraska can properly "file with the [DEA] Administrator a written notice of . . . intention to participate," 21 C.F.R. § 1308.44(b), in the hearing scheduled to commence on December 2, 2024. *See* 89 Fed. Reg. 70149.

As set forth in the DEA's notice of hearing, parties seeking to participate in the hearing must: (1) state with particularity their interest in the proceeding, (2) state with particularity the issues on which they desire to be heard, and (3) briefly state their position on those issues. 89 Fed. Reg. at 70149; *see also* 21 C.F.R. § 1316.48. Nebraska provides the required particularized statements below.

Nebraska's Interest Warranting Participation

Nebraska is a sovereign State that has enacted and enforces its own laws regulating and criminalizing the cultivation, manufacture, possession, sale, and trafficking of various controlled substances, including marijuana. *See generally* Neb. Rev. Stat. §§ 28-401 to 28-456.01 & 28-458

to 28-478. Under Nebraska law, marijuana is "illegal in all circumstances." Nebraska Comment at 4; *see also* 28 Neb. Rev. Stat. §§ 28-405(c)(8), (27)(A). Government entities in Nebraska—both state and local—"expend significant law enforcement, judicial system, and penal system resources . . . combat[ing] . . . [the] trafficking and transportation of marijuana" originating in one of the several States neighboring Nebraska where marijuana is legal at the state level. *Id*. at 4 n.11 (quoting *Nebraska v. Colorado*, 577 U.S. 1211, 136 S. Ct. 1034, 1036 (2016) (Thomas, J., dissenting from denial of motion for leave to file original jurisdiction complaint)). Because moving marijuana to Schedule III will "effectively provide the marijuana industry with a substantial tax cut," *id*. at 5, unlocking "billions in tax savings," *id*. at 34 n.86, rescheduling will allow the existing marijuana industry to "significantly expand their operations," *id*. at 36. Thus, rescheduling marijuana will "supercharge the marijuana industry," *id*., sending a "tidal wave of" marijuana "flooding into Nebraska," *id*. at 40.

This influx of marijuana will increase the many costs to and expenditures by Nebraska's law enforcement agencies, its judiciary, and its penal system directly related to or arising from marijuana. It will also exacerbate the numerous negative externalities that accompany increased marijuana consumption, externalities that harm Nebraska's public health, safety, and general welfare. *See id*. at 37–40. These externalities include rising rates of homelessness and crime, *id.*, increases in the number and severity of motor vehicle accidents, *id*. at 28–29, and a myriad of deleterious impacts on the health of Nebraska's citizens—impacts that are especially pronounced in children and adolescents, *id*. at 29–33.

Simply put, rescheduling marijuana would adversely affect Nebraska. Nebraska has an interest in facilitating factual development that could forestall the regulatory action that would lead to such harm. To the extent there is any question about the magnitude of harm rescheduling would inflict on Nebraska, participation at the hearing would also facilitate factual development regarding both the nature and extent of its negative impact.

Issues on Which Nebraska Desires to Be Heard and its Position on those Issues

The full breadth of Nebraska's legal objections (and related argument) regarding the propriety of the proposed rescheduling are set forth in its previously filed comment. *See generally* Nebraska Comment. Nebraska understands that the purpose of the hearing is factual development. *See* 21 C.F.R. § 1308.42. Indeed, the Notice of Proposed Rulemaking (NPRM) repeatedly noted the need for "additional information" and "expert opinion" on a variety of pertinent factual questions. *See*, *e.g.*, 89 Fed. Reg at 44601, 44610, 44613, 44615, 44622. In addition to the various subjects identified in the NPRM, Nebraska intends to provide evidence on factual matters including, but not limited to, the following:

1. *Marijuana's actual or relative potential for abuse* – The NPRM, relying on the recommendation of the Department of Health and Human Services (DHHS), suggests that "marijuana has a potential for abuse less than the drugs or other substances in schedules I and II." 89 Fed. Reg. at 44616. As outlined in its comment, Nebraska disagrees. *See* Nebraska Comment at 20–23. Nebraska intends to proffer evidence, likely including expert opinion testimony, tending

to show that marijuana has a high potential for abuse. *Id*. Such evidence would support marijuana's continued placement on CSA Schedule I.

2. *Whether marijuana has a "currently accepted medical use" (CAMU)* – Nebraska believes the NPRM incorrectly abandoned the prevailing five-part test for determining if a substance has a CAMU. *See* Fed. Reg. 44616–17; *see also* Nebraska Comment at 23–27. That said, assuming the NPRM's proposed alternative two-part test is adopted, Nebraska intends to offer evidence suggesting that there exists no CAMU for marijuana. This includes evidence that illustrates both the absence of an accepted threshold for safely using marijuana under medical supervision and the practical impossibility for setting such a threshold given the wide variety in marijuana strains and cultivars that precludes the ready prescription of a "consistent and predictable dose." *See* Nebraska Comment at 27. Nebraska also intends to offer evidence tending to show that the CAMU for marijuana purportedly found by HHS fails to satisfy even its newly relaxed two-part standard. *See id*. at 25–26. Such evidence would support marijuana's continued placement on Schedule I.

3. *The 811(c) factors, especially marijuana's effect on the public health and the impact of increased marijuana consumption on public safety and welfare* – When deciding on which schedule a drug or other substance belongs, the CSA requires consideration of eight factors. 21 U.S.C. § 811(c). Those factors include the "state of current scientific knowledge regarding the drug or other substance," "[i]ts history and current pattern of abuse," "[t]he scope, duration, and significance of abuse," and "[w]hat, if any, risk there is to the public health." *Id*. Nebraska intends to offer scientific evidence that reinforces the notion, discussed at length in its comment, that the current state of scientific knowledge regarding marijuana has not substantially changed since 2016, when the prospect of rescheduling marijuana was last contemplated (and rejected). *See* Nebraska Comment at 8–9, 19–23. Nebraska also intends to offer additional factual evidence, likely including expert opinion, tending to show that marijuana consumption has a serious negative impact on the public health. *See id*. at 28–33. Similar testimony would show, despite HHS's suggestion to the contrary, that marijuana's pattern of abuse resembles that of other Schedule I substances. *Id*. 20–23. Finally, Nebraska intends to offer evidence that tends to show that increased marijuana consumption creates negative externalities and "second order effects"—such as increased crime and homelessness, reduced workplace productivity, and the facilitation of the consumption of other "harder" drugs—that threaten not only the public health but also public safety and general wellbeing. *See id*. at 33–34, 37–40. This evidence, collectively, counsels against moving marijuana to Schedule III.

Conclusion

Nebraska's request to participate in the hearing should be granted. All notices concerning the hearing should be addressed to:

Zachary Viglianco
Nebraska Department of Justice
2115 State Capitol
Lincoln, NE 68509
zachary.viglianco@nebraska.gov

Respectfully submitted,

Mike Hilgers

Michael T. Hilgers
Attorney General of Nebraska

Americans for Safe Access

"Docket No. DEA-1362"
9/30/24

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Subject: Notice of Appearance

Dear Sir:

Please note that Steph Sherer would like to appear in the matter of Docket No. DEA-1362.

I am the founder and President of Americans for Safe Access Foundation (ASA), a nonprofit organization founded in 2002 with the mission of ensuring safe access to medical cannabis for therapeutic use and research. Over the last 22 years, ASA has utilized a variety of tactics, including legislation, education, litigation, research, grassroots empowerment, advocacy, and services for medical cannabis stakeholders to meet the immediate needs of patients while clearing the way for a national medical cannabis program. ASA coordinates stakeholders behind patient-centric strategies to address knowledge, policy, and regulatory gaps needed to integrate cannabis and cannabinoid medicines into U.S. healthcare.

ASA's members include medical cannabis patients in all 50 states. In 2012, the Federal Appeals Court for the DC Circuit heard oral arguments for *Americans for Safe Access v. Drug Enforcement Administration*, a lawsuit challenging the classification of marijuana as a dangerous drug with no medical value. In December 2016, ASA filed a "Request for Correction of Information Disseminated by DEA Regarding Marijuana (Cannabis) " utilizing the regulations of the Information Quality Act Request for Correction that resulted in the DEA removing incorrect information from their website. The request was based on contradictions to DEA's "The Dangers and Consequences) of Marijuana Abuse" and "Drugs of Abuse" and information provided by "DEA's Denial of Petition to Initiate Proceedings to Reschedule Marijuana" including claims that cannabis was a gateway drug, caused irreversible cognitive decline in adults, and contributed to psychosis and lung cancer.

ASA also provided guidance documents to the Food and Drug Administration (FDA) for the current rescheduling process and data that was used for the new approach to CAMU (memo can be found here)

(B)

DEA questions to the Justice Department's Office of Legal Counsel (OLC) suggest an objection to HHS' approach to 21 U.S.C. 811(c) and skepticism that their concerns raised throughout the DOJ's notice of proposed rulemaking document will be addressed during the public comment process or an administrative hearing. Furthermore, many of DEA's comments reference data in HHS' 2015 "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act" and DEA's 2016 "Denial of Petition to Initiate Proceedings to Reschedule Marijuana.6" While Schedule III may seem like a significant deviation from the recommendations provided in these documents, it is our hope that the DEA considers the enormity of the scientific and medical discoveries that have happened in the time since they were issued, as well as the vast societal need for an updated approach to cannabis policy as they make their determination. On behalf of our members, we would like to bring this date before the OAJL.

Headquarters:
1629 K Street Northwest Suite 300
Washington, DC 20006-1631
americansforsafeaccess.org

888 929 4367
facebook.com/safeaccessnow
@SafeAccess
@americansforsafeaccess

Americans for Safe Access

(C) Steph Sherer is founder and President of Americans for Safe Access (ASA), the largest national member-based organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research.

Her direct experience with the medical benefits of cannabis and her political organizing background led Steph to form ASA in 2002 with the purpose of building a strong grassroots movement to protect patients and their rights. As a powerful advocate, a skilled spokesperson, and an energetic initiator of campaigns, Steph has trained over 100,000 individuals across the country on civic engagement.

Steph has become the foremost international leader and expert on medical cannabis patient advocacy and, alongside the American Herbal Products Association (AHPA), has created the first industry standards in the areas of distribution, cultivation, analytics, and manufacturing, packaging, and labeling.

All notices to be sent pursuant to this appearance should be addressed to:

Steph Sherer

1629 K Street NW, Suite 300,

Washington, DC, 20006-1631

Respectfully yours,

September 30 2024
Attn: Administrator
8701 Morrissette Drive, Springfield, VA 22152

Dear Administrator,

Please take notice that I, Stephen J Mandile will appear in the matter of: Drug Enforcement Administration hearing with respect to the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act. Docket No. DEA-1362

(A) (State with particularity the interest of the person in the proceeding.).

My name is Stephen Mandile. I am a US Army Veteran, with a 100% service connected disability rating from injuries I sustained in 2005 while serving in Operation Iraqi Freedom III, in Iraq. Along with many other Veterans enrolled in the Dept. of Veterans Affairs health care I was prescribed many toxic medications. From 2005 - 2015 I had been prescribed 9 different opioids, with the last 6 years being prescribed fentanyl and oxycodone. My addiction lead to a failed suicide attempt. In 2015 I made the switch from those medications to using medical marijuana and I am a registered patient in the Massachusetts medical marijuana program.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

Due to the federal prohibition of cannabis, when I made the switch from opioids to cannabis I went from not having to pay for any of my pain medications to having to pay hundreds of dollars a week. Also, while I could travel all across the United States with my VA prescribed narcotics, it is illegal for me to cross state lines or get on an airplane with my medical cannabis.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

Marijuana has many medical uses which myself and countless other Veterans benefit from, without the side effects of overdose, coma, respiratory failure, or death. For those reasons marijuan should not be a schedule 1 substance

All notices to be sent pursuant to this appearance should be addressed to:
Stephen J Mandile
27 Henry Street
Uxbridge, Massachusetts

Respectfully yours
Stephen J Mandile

sSdp
Start making sense™

2370 Champlain St NW, Suite 12
Washington, DC 20009
202-393-5280

ssdp.org

September 30, 2024

Drug Enforcement Administration
Attn: Hearing Clerk/OALJ, Administrator
8701 Morrissette Drive,
Springfield, Virginia 22152

Subject: Notice of Appearance in Docket No. DEA-1362

To Whom It May Concern:

Please take notice that Kat Murti will appear in the matter of Docket No. DEA-1362, on behalf of Students for Sensible Drug Policy (SSDP), of which she is Executive Director.

Interest of the Person in the Proceedings

Students for Sensible Drug Policy (SSDP) is the largest national youth-led organization that advocates for ending the War on Drugs. Our network spans numerous campuses and communities, and we represent a broad coalition of students and young people affected by current drug policies.

Since 1998, SSDP has mobilized tens of thousands of young people to advocate for a more sensible approach to drug laws, and our members and alumni have been involved in every major marijuana legalization campaign in the past two decades.

SSDP has a significant interest in this proceeding because the rescheduling or descheduling of marijuana impacts the lives of the young people we represent, particularly regarding criminal justice, education, and access to marijuana for medical and adult use.

In April of 2024, our student and youth members helped mobilize the largest bipartisan coalition of marijuana advocacy, industry, and grassroots organizations in U.S. history. Our members made contact with every single office in both the Senate and the House of Representatives in support of descheduling marijuana, educating elected officials and their staff about the ways in which the criminalization of marijuana negatively impacts our members, including by obstructing our members' ability to obtain employment, education, and housing. Moreover, SSDP members who were formerly incarcerated for marijuana offenses spoke at a series of in-person and virtual educational events, including a vigil in front of the White House, about the need for descheduling, highlighting the lifelong harms that come with criminalization of marijuana as a controlled substance, and the inadequacy of recent executive actions intended to remedy that harm.

2370 Champlain St NW, Suite 12
Washington, DC 20009
202-393-5280

ssdp.org

SSDP submitted a public comment on FR Doc # 2024-11137 on July 22, 2024 (DEA-2024-0059-39694) urging the Department of Justice end the decades-long War on Marijuana—which we believe to be the intent of rescheduling—by completely removing marijuana from the Controlled Substances Act (CSA).

SSDP also submitted a public comment on FR Doc # 2024-11137 on July 22, 2024 (DEA-2024-0059-41424) as a member of the United for Marijuana Decriminalization (UMD) coalition calling on the federal government to end the criminalization of marijuana by descheduling it from the Controlled Substances Act, as well as a public comment on FR Doc # 2024-11137 on May 28, 2024 (DEA-2024-0059-6375) as a member of the Marijuana Justice Coalition (MJC) in the form of a letter sent by the MJC to President Biden and Vice President Harris encouraging the descheduling of marijuana from the CSA.

SSDP also helped create, promote, and operate a public comment tool through which 10,327 of the total 42,925 public comments on FR Doc # 2024-11137 were submitted, a significant number of which were submitted by SSDP members and alumni.

Objections and Issues to Be Addressed

While SSDP commends the Department of Justice for taking a much-needed step towards ending federal marijuana prohibition and believes Schedule III is much more appropriate than Schedule I, rescheduling marijuana as a Schedule III drug simply is not sufficient.

SSDP objects to the limited scope of rescheduling marijuana as a Schedule III controlled substance and urges the Department of Justice to remove marijuana from the Controlled Substances Act (CSA) entirely ("descheduling").

We desire to be heard on the following issues:

- Support for marijuana to be removed from Schedule I of the Controlled Substances Act, which does not align with marijuana's relatively low potential for abuse, widely accepted medical use, and relative safety of use.
- The failure of Schedule III to accomplish the political will of the American people despite the large and growing consensus across all demographic segments, geographic regions, and political affiliations that marijuana prohibition has utterly failed in its stated goals.
- The continued criminalization of marijuana possession and use, even under Schedule III, which disproportionately affects young people and marginalized communities.
- The impact on research, public health, and economic opportunities for youth if marijuana remains a controlled substance.

Position Regarding the Objections or Issues

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202-393-5280

ssdp.org

As stated in our public comment on FR Doc # 2024-11137 (DEA-2024-0059-39694), SSDP believes that rescheduling marijuana to Schedule III is insufficient and does not address the harms caused by prohibition, particularly those that most impact the young people we represent.

While moving marijuana from Schedule I to Schedule III of the Controlled Substances Act (CSA) would be an improvement over current policy, it does not accomplish the stated goals of the Biden Administration in directing the Department of Health and Human Services (HHS) to conduct a review of how marijuana is classified and it will not sufficiently address the ongoing harms caused by marijuana criminalization.

Our position is that the only effective solution is to fully deschedule marijuana, thereby removing it from the CSA.

This would ensure that young people are not criminalized for marijuana-related activities, facilitate many important state functions and allow state-legal industries to flourish without federal interference, and pave the way for comprehensive drug reform rooted in justice and public health.

Conclusion

SSDP looks forward to the opportunity to participate in this hearing to advocate for a more sensible and compassionate approach to drug policy, one that aligns with the will of the American people and addresses the ongoing harm caused by marijuana criminalization.

All notices to be sent pursuant to this appearance should be addressed to:

Students for Sensible Drug Policy (SSDP)
% Kat Murti, Executive Director
1800 M St NW, #33051
Washington, DC 20036

Respectfully yours,

Kat Murti
Executive Director
Students for Sensible Drug Policy (SSDP)

Start making sense™

AFNA
Association of Federal Narcotics Agents
www.afna.org

Drug Enforcement Administration
Attn: Honorable Anne Milgram, Administrator
870 I Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA–1362

September 23, 2024

Honorable Administrator Milgram-

As the organization who represents retired and active Drug Enforcement Administration (DEA) Agents and additional DEA employees, again both retired and active, the Drug Enforcement Association of Federal Narcotics Agents (DEAFNA) is keenly situated to be identified as interested persons at a hearing on the matter related to Docket No. DEA-1362 concerning the rescheduling of Marijuana from Schedule I to Schedule III of the Controlled Substances Act. As an interested party adversely affected by this proposed change, we respectfully request a hearing to present evidence demonstrating that marijuana does not meet the criteria for rescheduling.

Specifically, we intend to present factual evidence and expert testimony showing that marijuana fails to satisfy the five key criteria established by the FDA for determining if a substance has a currently accepted medical use:

- Known and reproducible chemistry: Unlike pharmaceutical drugs, marijuana's chemical composition is highly variable and not standardized.
- Adequate safety studies: Recent research linking marijuana use to increased risks of psychosis and mental illness raises serious safety concerns that warrant further investigation.
- Well-controlled efficacy studies: The limited studies cited by the FDA to justify rescheduling are flawed and insufficient to demonstrate efficacy for medical use.
- Expert acceptance: Major medical organizations like the American Psychiatric Association have stated that marijuana can worsen certain psychiatric conditions, indicating a lack of expert consensus on its medical utility.
- Widely available scientific evidence: There is insufficient high-quality scientific data to conclusively establish marijuana as medicine, and medical experts do not agree on its therapeutic value.

We believe this evidence demonstrates that marijuana does not meet the statutory requirements for rescheduling to Schedule III at this time.

In addition, as stated above, DEAFNA is comprised of retired and active DEA agents, who unquestionably understand this issue from every perspective. In fact, DEA agents are the only federal employees whose sole mission since 1973 has been to enforce the controlled substances laws and regulations of the United States. We are adamantly opposed to any intentional move that we predict will have such a drastically negative and permanent impact on public safety and health. We respectfully request the opportunity to present these facts and expert opinions in greater detail at a hearing on this matter.

Thank you for your consideration. Please let me know if you require any additional information regarding our standing as an interested party or the evidence we intend to present.

Sincerely,

M Marshall Fisher

Marshall Fisher
President Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)
marshallfisher@rocketmail.com

AFNA
P.O. Box 2801
Ashburn, VA 20146

09/26/24 X FILED

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24 SEP 2024 22 2 L

Thinking of You STATION FREEDOM

Drug Enforcement Administration,
Attn: Administrator, 8701 Morrissette
Drive, Springfield, Virginia 22152

22152-108001

September 30, 2024

T. Christopher Wright
2114 E. 35th St.
Minneapolis, MN 55407
tc_wright38@yahoo.com

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152
(571) 362-3249
nprm@dea.gov

RE: Docket No. DEA-1362

Dear Administrator,

In my view as a cannabis legalization activist for over 38-years, while it is preferable to reschedule cannabis from Schedule I to Schedule III rather than leave cannabis in Schedule I, cannabis should be more correctly removed from the CSA completely and added to subtitle E of the Internal Revenue Code of 1986, like distilled spirits, wine, absinthe, malt beverages, nicotine, and tobacco or placed in Schedule V of the CSA.

In 1988, the DEA's Chief Administrative Law Judge Francis L. Young, ruled in the Marijuana Rescheduling Petition hearing that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." Therefore, one of the safest therapeutically active substances known to man should be correctly classified in Schedule V with the least dangerous substances with known medical uses if left in the CSA.

Sincerely,

T. Christopher Wright

TENNESSEE BUREAU OF INVESTIGATION
901 R.S. Gass Boulevard
Nashville, Tennessee 37216-2639
(615) 744-4000
Facsimile (615) 744-4500
TDD (615) 744-4001

BILL LEE
GOVERNOR

DAVID B. RAUSCH
DIRECTOR

September 30, 2024

Drug Enforcement Administration
Attn: Matthew Strait
8701 Morissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-1362

Dear Mr. Strait:

I was surprised to receive your September 17, 2024, letter (Letter) asking the Tennessee Bureau of Investigation (TBI) to demonstrate that it is an "interested person" and asking TBI to identify relevant information that it intends to present at the hearing about the Department of Justice's (DOJ) proposed rescheduling of marijuana to Schedule III (Proposed Rule). 89 Fed. Reg. 44,597. TBI works directly with DEA in enforcing federal drug laws— its interested party status is facially apparent. In addition, the Proposed Rule openly invites "interested persons" to provide evidence at the hearing; however, DEA is now requesting to prescreen this evidence when it has failed to perform the required eight-factor analysis (8FA). Indeed, when DEA last performed the 8FA in 2016, it declined to reschedule marijuana, and without a full 8FA for the current hearing, there can be no intervening evidence that would change this result.
Nonetheless, to avoid waiving its ability to present evidence at DEA's hearing on the misguided Proposed Rule, TBI provides the following response to your Letter.

I. TBI is undisputably an interested party.

Under 21 C.F.R. § 1300.01(b), an interested party is any "any person adversely affected or aggrieved by" a rule or proposed rule.[1] As Tennessee's lead investigative agency with original jurisdiction over drug enforcement and the primary agency for forensic science services for law enforcement in the State, TBI is adversely affected by the Proposed Rule.

The Proposed Rule would adversely affect TBI operations. TBI's drug enforcement operations are supported by the Tennessee Dangerous Drugs Task Force, which works closely with federal agencies (including the DEA) to combat drug crimes across the State. TBI both investigates and enforces federal and state drug-related offenses, including marijuana offenses. For example, TBI's forensic crime laboratories receive and process more than 30,000 drug submissions annually, a significant number of which are marijuana-related. Indeed, TBI is one of few state

[1] The Proposed Rule is purportedly authorized by 21 U.S.C. § 811. 89 Fed. Reg. 44,622.

agencies performing THC quantification in its crime labs. This work is complicated by the increasing prevalence of genetically modified and synthetically manipulated marijuana. Rescheduling marijuana (making use more widespread) would strain drug-enforcement activities. Accordingly, the Proposed Rule would have an immediate and adverse impact on TBI, requiring it to spend time and resources reevaluating enforcement priorities, personnel assignments, and asset allocation in response to any rescheduling.

The Proposed Rule would adversely impact TBI's mission. Additionally, the Proposed Rule would impair TBI's mission to ensure the safety and welfare of Tennessee's citizenry and residents. Marijuana-related crimes account for at least half of the drug-related crimes in Tennessee, including assaults, thefts, burglary, and murder. Furthermore, states with medical and recreational marijuana legalization have experienced significant difficulties arising from organized crime's exploitation of the marijuana market. These concerns are particularly poignant in Tennessee, which plays a crucial role as a hub in the country's transportation and logistics network due to its geographic location within the United States.

Legalization of marijuana in other states has also led to increased marijuana-related incidents among juveniles and higher rates of cannabis-related calls to poison control centers.[2] Even without rescheduling or legalization, Tennessee has already seen a sharp rise (200+ incidents since 2020) in reported non-fatal overdoses and severe adverse medical reactions to cannabis, particularly among youth, impacting schools and emergency services. TBI's experience also supports the "gateway hypothesis" that marijuana use, especially among adolescents, may lead to abuse of other harmful substances, including opioids. Peer-reviewed research also supports this hypothesis.[3]

Accordingly, the Proposed Rule adversely affects TBI's operations and ability to promote public health and safety. TBI is undoubtedly an "interested person" as defined in 21 C.F.R. § 1300.01(b).

II. TBI has material evidence that the Proposed Rule does not address.

Your Letter also asks TBI to elaborate on the evidence TBI would present at hearing. Because the Proposed Rule repeatedly invites additional data on "routes of administration of marijuana and the impact on Δ9-THC potency," I will focus on that evidence here. 89 Fed. Reg. 44,607; *see also id.* at 44,614. For a more thorough list of TBI's concerns and the evidence underlying them, I would refer you to TBI's comment letter ("Comment Letter").[4]

Marijuana is increasingly offered in various and innocuous forms. As marijuana has become increasingly deregulated and legalized by various States, it has also become more available in

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[2] *The Legalization of Marijuana in Colorado: The Impact, Volume 8, September* 2021, Rocky Mountain HIDTA.

[3] *See, e.g.*, Arthur Robin Williams, *Cannabis As A Gateway Drug for Opioid Use Disorder*, 48 J.L. Med. & Ethics 268 (2020); Roberto Secades-Villa et al., *Probability and Predictors of the Cannabis Gateway Effect: A National Study*, 26 Int'l J. Drug Policy 135 (2015).

[4] *Available at* https://downloads.regulations.gov/DEA-2024-0059-34513/attachment_1.pdf.

forms that are indistinguishable from their non-THC containing equivalents, including vapes and edibles. These are often marketed toward young adults and children who are particularly vulnerable to overdose due to lower body weight and heightened sensitivity to THC. This risk is amplified by the delayed effects of THC edibles, which may mislead the user into concluding the initial dose was insufficient. Loosening marijuana regulations will make policing such deceptive and dangerous marketing significantly more difficult. The Proposed Rule does not consider the dangerous impact of these methods of conveying and administering marijuana.

Marijuana is increasingly potent. The potency of Δ9-THC in marijuana has skyrocketed in recent years, from around 3% in the 80's and 90's to as high as 42% in 2021. Comment Letter at 3. THC infused edibles can reach potency levels as high as 98%. *Id.* The Proposed Rule briefly acknowledges that the potency of marijuana has "increased dramatically," 89 Fed. Reg. 44,604, but nowhere addresses the impact of such increased potency on users or public health. TBI has firsthand information about the prevalence of such high-potency marijuana and its effects.

III. DEA should grant TBI's request for hearing.

In conclusion, TBI is an interested party that can provide additional information that the Proposed Rule invites. I anticipate that DEA will grant TBI's request for a public rehearing regarding the Proposed Rule.

Respectfully yours,

David B. Rausch
Director

Cc: Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morissette Drive
Springfield, VA 22512

TRAINING MARBLES, INC.
There is no substitute for EXPERIENCE

Date: September 30, 2024
To: Drug Enforcement Administration
8701 Morrissette Drive,
Springfield, VA 22152

Docket No. DEA-1362

Attn: Anne Milgram, Administrator

Subject: Request to be heard

Dear Administrator Milgram,

I am writing to formally express my interest in participating in the upcoming hearing regarding the rescheduling of marijuana in the Controlled Substance Act (CSA). As a Human Resources professional and subject matter expert with 26 years of experience implementing Drug-Free Workplace programs for thousands of employers who are adversely affected by the rescheduling, I can provide valuable insights into the potential implications of this change on workplace safety.

While the focus is often on the Department of Transportation (DOT), it is equally important to consider NON-DOT industries that adhere to DOT 49 CFR Part 40 guidelines. The NON-DOT businesses, specifically those in safety-sensitive industries (police, fire, nursing, etc.), will likely be adversely affected in the following manner:

1) Increase in workplace injuries and death.
2) Legal exposure due to lack of clarity in drug testing regulations and lack of clarity regarding the interactive process under the Americans with Disabilities Act (ADA).

The rescheduling of marijuana, while in line with evolving social and medical perspectives, necessitates the establishment of explicit drug testing provisions and impairment protocols. This is to ensure workplace safety and compliance, especially in industries that heavily rely on drug testing guidelines.

I urge the Drug Enforcement Agency (DEA) and Department of Justice (DOJ) to collaborate with the U.S. Department of Health and Human Services (HHS) to ensure that testing standards remain in place and reflect the evolving legal landscape. This is not just to protect

Phone: (614) 204-6834
Fax: (614) 239-8288
Web: www.TrainingMarbles.com

the workplace but also the general public at large, as any compromise in safety could have serious consequences.

I would like to address the following points:

1) Amend E.O. 12564 section 7(c) to grant HHS authority to conduct drug testing for marijuana if moved to a Schedule III drug under the CSA.
2) Establish guidelines that eliminate testing for non-psychoactive cannabis metabolites to fill the current gap in testing abilities.
3) Define comprehensive guidelines, including protocol for impairment and safety-sensitive provisions, prior to rescheduling.
4) Define comprehensive guidelines for the interactive process under the Americans with Disabilities Act (ADA)
5) Authorize employers to take adverse actions against employees who are impaired in the workplace.

By adopting these measures, the DEA can protect workplace safety while respecting the medical use of marijuana. It is crucial to strike a balance that prioritizes safety and provides clear guidelines for employers to manage impairment issues.

I appreciate your consideration of my request to participate in these discussions. It is essential to ensure that the transition to a Schedule III classification does not undermine employers' ability to enforce drug-free workplace policies or compromise safety standards.

Thank you for your attention to this critical issue. I look forward to your response and the opportunity to provide further input on behalf of employers and safety professionals nationwide.

Best Regards, Dyann

Dyann McDowell, President, HR Business Partner and Trainer
Training Marbles. Inc.

Phone: (844)362-7253 ext. 1
Cell: (614)204-6834
Email: dmcdowell@trainingmarbles.com

United States Cannabis Coalition
PO Box 329
Marietta, OK 73448

September 30, 2024

Drug Enforcement Agency
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Docket No. DEA-1362

Attn: Administrator

Dear DEA Schedule III Review Committee,

I am writing to formally request a meeting and/or to participate in the public hearing with the Drug Enforcement Administration (DEA) to discuss the critical issue of cannabis rescheduling under the Controlled Substances Act. With both scientific evidence and shifting societal attitudes in mind, cannabis's current Schedule I classification is no longer tenable.

While the rescheduling of cannabis—potentially to Schedule III—would represent progress compared to its current status, I must caution against this option as it may introduce new complications. Schedule III substances are recognized for medical use but are also considered to have a moderate to low potential for abuse and physical/psychological dependence. If cannabis were placed under Schedule III, it would still be subject to an intricate web of regulatory restrictions, limiting patient access and hindering the growth of a legitimate, regulated cannabis industry.

Moreover, rescheduling cannabis to Schedule III could perpetuate many of the same law enforcement and criminal justice challenges we currently face under Schedule I. Police might still use the presence of cannabis as probable cause for searches and arrests, while individuals could continue to face felony charges for possessing or distributing amounts above arbitrary thresholds. This would do little to address the underlying issues tied to cannabis prohibition.

The most reasonable path forward is the complete de-scheduling of cannabis from the Controlled Substances Act. This approach, which aligns with both the Democrat-sponsored Marijuana Opportunity Reinvestment and Expungement Act (H.R. 3617) and the Republican-sponsored Common Sense Cannabis Reform for Veterans, Small Businesses, and Medical Professionals Act (H.R. 1017), would allow states to regulate cannabis as they see fit in accordance with the 10th Amendment of the U.S. Constitution. Full de-scheduling would remove barriers to research, open access for medical purposes, and promote the development of a

United States Cannabis Coalition

legitimate, safe cannabis industry. It would also end the racially disparate enforcement and criminalization that has defined the failed "War on Drugs."

I believe a comprehensive and evidence-based review by the DEA will support the case for full de-scheduling. For this reason, I am formally requesting an in-person meeting to discuss this matter further, as well as a public hearing where medical experts, patients, and other stakeholders can provide testimony on this important issue.

The health, well-being, and rights of the American people are at stake. I look forward to working constructively with the DEA to establish a more sensible path forward for cannabis policy. Please let me know how I can assist in facilitating this process.

Thank you for your attention to this critical issue.

Sincerely,

Patrick Hiram Moore

Director, United States Cannabis Coalition

usacannabiscoalition@gmail.com

831-229-0399

Patrick H. Moore
PO Box 329
Marietta, Ok 73448

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Springfield, VA 22152

22152-108001

Shane Pennington
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2020 K Street, NW
Suite 600
Washington, D.C. 20006

Direct: 202.778.3005
Fax: 202.778.3063

September 30, 2024

CERTIFIED MAIL - RETURN RECEIPT REQUESTED
VIA ELECTRONIC MAIL TO: nprm@dea.gov

Drug Enforcement Administration
Attn: Administrator Milgram
8701 Morrissette Drive
Springfield, VA 22152

Re: **Request to Participate in a Hearing & Notice of Appearance**
Docket No. DEA-1362 // Rescheduling of Marijuana

Administrator Milgram:

Pursuant to 21 C.F.R. §§ 1308.44(c) and 1316.48, our client, Village Farms International Inc. ("Village Farms"), submits, as an "interested person" under 21 C.F.R. § 1300.01(b), this Notice of Desired Participation and Notice of Appearance. Village Farms is prepared to submit declarations regarding the expert and fact-witness testimony that Village Farms would, if so permitted, present for consideration in the rescheduling hearing. Support for Village Farm's interested person status and participation is elaborated below.

I

On May 21, 2024, the Drug Enforcement ("DEA") issued a Notice of Proposed Rulemaking which, as proposed, would transfer marijuana's listing under the Controlled Substances Act ("CSA") from schedule I to schedule III.[1] In support, the DEA largely relies on the Department of Health and Human Services' ("HHS") view that marijuana has currently accepted medical uses and low levels of abuse potential or psychological dependence relative to substance in schedules I and II.[2] Pertinently, if the rescheduling is achieved, marijuana would be subject to, in addition to pre-existing treaty requirements, schedule III control requirements instead of schedule I requirements.[3]

On August 29, 2024, the DEA published notice in the Federal Register that it will hold a hearing on the Proposed Rule.[4] As stated in the Notice of Hearing, the purpose is to "'reciev[e] factual evidence and expert opinion regarding' whether marijuana should be transferred to schedule III of the list of controlled substances."[5] The Notice of Hearing requires every interested person who wishes to participate in the hearing, set for December 2, 2024, to file a written notice of their desired participation.[6] This notice must also specify with particularity: (i) the interest of the person in the proceeding; (ii) the objections or

[1] *See Schedules of Controlled Substances: Rescheduling Marijuana*, 89 Fed. Reg. 44597 (proposed May 21, 2024) (to be codified at 21 C.F.R. 1308.13) (the "Proposed Rule").
[2] *Id.*
[3] *Id.*
[4] *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148 (August 29, 2024) ("Notice of Hearing").
[5] *Id.* (quoting 21 C.F.R. § 1308.42).
[6] *Id.*; *see also* 21 C.F.R § 1308.44(c) (holding that to participate in a hearing, an interested person may file a request to participate).

issues concerning that which the person desires to be heard; and (iii) the position of the person regarding the objections or issues.[7]

II

Village Farms is the parent company of Balanced Health Botanicals, LLC ("Balanced Health"), a wholly-owned United States limited liability company, and two wholly-owned Canadian subsidiaries: Rose Bioscience and Pure Sunfarms Corporation ("Pure Sunfarms"). Pure Sunfarms operates in the Canadian marijuana production and research industries and runs one of the largest cannabis operations in the world. Rose Bioscience also operates in the Canadian marijuana market and has recently expanded internationally to the Netherlands, where it holds one of ten manufacturing licenses. Domestically, Village Farms intends to enter the U.S. marijuana market through its Balanced Health subsidiary by leveraging one of the largest greenhouse operations in the country with the operational and product expertise it has gained through Pure Sunfarms' success in Canada. Balanced Health already has a fully licensed, operational grow house in Texas and can begin production for research or retail purposes once licensed and approved by the DEA. Consequently, the Proposed Rule and any associated hearings directly and significantly impact Village Farms' operations.

Village Farms is prepared to offer substantial evidence for the ALJ to consider. Not only has Village Farms gained expertise as to the efficacy, safety, and dependency risk of marijuana through its Canadian operations, but it is uniquely situated to share its expertise as a marijuana production and research entity. Specifically, Village Farms would introduce testimony and evidence as to the impact the potential rescheduling would have on the legal marijuana market. Because of marijuana's current scheduling, other marijuana producers and researchers are unable to provide similar evidence,[8] making Village Farms' participation crucial to the Administrative Law Judge's ("ALJ") and DEA's ability to optimize any eventual final rule.

Specifically, Village Farms wishes to introduce evidence on several of the eight factors that guide the Administration's determination of whether to reschedule marijuana. As outlined in the Proposed Rule, those eight factors are: (1) the actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect; (3) the state of current scientific knowledge regarding the drug or other substance; (4) the history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) the risk to public health; (7) psychic or psychological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled.[9] Village Farms wishes to introduce evidence as to the following effects:

- ***The Actual or Relative Potential for Abuse is Lower than that of Comparator Substances.*** Through Village Farms' extensive research, conducted under its Canadian subsidiary, it has been able to compile substantial evidence demonstrating that marijuana's actual or relative potential for abuse is much lower than that of the comparator substances such as heroin (schedule I) or cocaine and fentanyl (schedule II). Because Village Farms has been able to conduct extensive research alongside leading Canadian researchers—using its own production strains which have entered the Canadian market—the evidence Village Farms possess on this point is unlikely to be duplicative of that of other participants. Similarly, this evidence will be useful in the ALJ's analysis of the seventh factor, the psychic and psychological dependence liability involved in marijuana use.

[7] *Id.* at 70149.
[8] *Cannabis Policies for the New Decade Before the Subcomm. on Health H. Comm. on Energy and Commerce* 116 Cong. 8-9 (2020) (Statement of Nora Volkow, M.D., Director, National Institute on Drug Abuse).
[9] *See* Proposed Rule at 44599; 21 U.S.C. § 811(c).

- ***Scientific Evidence of Marijuana's Pharmacological Effect.*** Through the same studies, Village Farms has been able to gather evidence of marijuana's pharmacological effects as to both medicinal and as a recreational uses. Village Farms' Canadian subsidiary has been able to produce and research its own strains and the impact caused by widespread use of the its product. Consequently, Village Farms' research is precise to a measure unparalleled by U.S.-based researchers, whom, until recently, have only been able to obtain supply distributed by the National Institute on Drug Abuse, which often distributes strains not in general use and that contains contaminants.

- ***The State of Current Scientific Knowledge.*** Through its extensive clinical research, Village Farms is able to provide international insight that U.S.-based participants cannot provide due to the current restrictions on the production, distribution, and research of marijuana. Notably, Village Farms has extensive knowledge of the leading scientific practices currently utilized internationally in the cultivation and research of both medicinal and recreational marijuana.

- ***Risk to Public Health.*** Through its extensive research and its experience producing and distributing marijuana for medicinal and recreational purposes, Village Farms is uniquely poised to offer evidence as to the low risk marijuana poses to public health. In fact, because of the current regulatory landscape in the United States, Village Farms may be the only entity that can present evidence concerning widespread use of marijuana products and public health.

Not only does Village Farms intend to produce the evidence described above in support of its position that marijuana does not belong in schedules I or II, but, this rulemaking also directly impacts Village Farms' domestic operations and research.

III

Beyond the requirements for involvement enumerated in the Proposed Rule, Village Farms qualifies as an "interested person" under both DEA regulations and legal precedent. Village Farms both falls within the relevant "zone of interests" and would face adverse consequences should the rescheduling fail.

A

The Proposed Rule is a "scheduling action," as defined by 21 U.S.C. § 811(a).[10] As such, the Proposed Rule is subject to the Administrative Procedure Act ("APA").[11] The APA provides that, "So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding . . . in connection with an agency function."[12]

An "interested person," according to DEA regulations, is one that is "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. § 811]."[13] While adversely affected or aggrieved is not defined, the DEA holds that a person is adversely affected or aggrieved—and is therefore an interested person—when they fall within the zone of interests regulated by the CSA.[14] The DEA further holds that a

[10] *See* Proposed Rule at 44,598; 44,621.
[11] *Id.* at 44,598.
[12] 5 U.S.C. § 555(b).
[13] 21 C.F.R. § 1300.01(b); *see also* 21 C.F.R. § 13001.01(b) (defining "person" as including "any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.").
[14] Exhibit A ("ALJ Order").

person is within the zone of interests "if they are regulated by the particular agency action being challenged, or if they are considered protected by the statute in question."[15] This is not a difficult burden to meet, and the Supreme Court has held that the zone of interests test is "not meant to be especially demanding" as Congress intended "to make agency action presumptively reviewable."[16]

B

Here, Village Farms falls within the zone of interests regulated by the CSA. As DEA is aware, the CSA controls every aspect of production, transportation, and distribution of controlled substances. Because marijuana is currently a schedule I drug, importers, manufacturers, and producers are subject to a demanding series of requirements that relate to the growing, procurement, and storage of marijuana. For example, producers must provide the DEA with accurate production estimates, must utilize top-of-the-line storage and protection systems, and must comply with extensive application requirements to obtain a DEA license—which in turn may require simultaneously obtaining multiple, dually-required licenses. These compliance mechanisms are often prohibitively expensive, preventing many from entering this market. In turn, this barrier to entry delays and deters the development and advancement of safe and reliable marijuana products.

If, however, the Administration were to reschedule marijuana to a schedule III drug, these barriers would be lowered to a point that allows for wider market entry and development. While still subject to the DEA's control and diversion requirements, such schedule III mandates are relaxed enough that organizations like Village Farms could make effective entry into the market. Rescheduling will also allow for further research into marijuana strains and products actually used by the general public. Already, 38 states, the District of Columbia, and four territories have legalized the use of medical marijuana, and numerous states have legalized recreational use. Consequently, there exists a broad market for the development and sale of safe marijuana substances for use in both medical and recreational capacities. No matter the outcome of the hearing and ultimate Final Rule, this industry will be significantly impacted.

Among the regulatory barriers that would be relaxed if marijuana were moved from schedule I to schedule III are:

- The fact that research with schedule I substances requires an FDA-approved protocol—an arduous and costly requirement that does not apply to research with substances in any other schedule.[17]
- The inventory requirements for substances in schedules I and II are significantly stricter than those applicable to substances in schedule III.[18]
- The export requirements that would apply to marijuana were it transferred to schedule III are significantly less strict than those that apply to it currently under schedule I.[19]
- The restrictions on orders for schedule I and II substances are significantly stricter than those applicable to substances in schedule III.[20]

[15] ALJ Order at 5 (quoting *MD Pharm. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)).
[16] *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012).
[17] *See* 21 C.F.R. § 1301.18.
[18] *See id.* § 1304.11(e)(6).
[19] *See id.* § 1312.21.
[20] *See, e.g.*, *id.* §§ 1305.04, 1305.21.

For years Village Farms has sought to have its products researched by a DEA-registered researcher in the United States and has even contemplated applying for its own bulk manufacturing and/or research license. These goals have been significantly impeded by the costs and uncertainties associated with marijuana's schedule I status under U.S. federal law. Transferring marijuana to schedule III will relax those requirements, increase the level of certainty regarding marijuana's regulatory status under federal law, and, resultantly, expedite and enhance Village Farms' likelihood of success in achieving its research and production goals in the United States.

Finally, marijuana's schedule I status impedes Village Farms' business interests by making it impossible for Village Farms to enter the U.S. market without risking its own status as a publicly traded company. While moving marijuana to schedule III would not solve that problem immediately, Village Farms believes it would go a long way toward reducing the perceived risk associated with doing business with marijuana companies in general. It would, in other words, be an important first step toward permitting Village Farms to enter the U.S. market. That is a goal that the Administration should support because high-quality, highly-regulated products like those Village Farms offers are far safer to the public than the unregulated ones that are currently available to U.S. consumers due to federal prohibition. At the very least, moving marijuana to schedule III would make it easier for Village Farms to test—and, we believe, prove—this public-safety-focused thesis.

IV

In conclusion, Village Farms hereby notices its intent to participate in the DEA's ALJ hearing dated December 2, 2024. Village Farms maintains a significant stake in the outcome of the proceeding, and intends to present evidence on 5 of the 8 factors that guide the Administration's determination of the rescheduling of marijuana. Significantly, the evidence Village Farms can provide is a result of its operations in the Canadian cannabis industry, and is therefore unlikely to be duplicative of any other evidence presented at hearing. In fact, Village Farms' research, experience, and participation in a nationally legalized marijuana market will contribute insight, data, and evidence that is unable to be obtained elsewhere.

Not only does Village Farms intend to produce evidence for the Administration's consideration, it also will be significantly impacted by the outcome of this administrative process. As Village Farms has already purchased operational resources in the U.S., it now requires legal access into the market to conduct its production and research goals. The current schedule I requirements impose a significant barrier to this entry. The rescheduling to a schedule III drug, however, would alleviate many of the barriers currently in place—while still maintaining adequate diversion and safety controls—allowing for Village Farms and several other entities to enter the market and begin to develop safe and effective marijuana products. With various states recently adopting laws enabling both medicinal and recreational marijuana use, the research of strains actually in use is critical to providing safe consumption. Village Farms stands uniquely ready to fulfill these requirements and therefore maintains a significant interest in the outcome of this proceeding.

For these reasons, Village Farms respectfully requests the ability to participate in the rulemaking process to the fullest extent permissible by law—including the December 2, 2024 hearing.

All notices and correspondences to be sent pursuant to this appearance should be addressed to the undersigned.

Very truly yours,

Shane A. Pennington
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SAP:ttc
Encl.

Outlook

[EXTERNAL] RE: DEA Hearing Request

From Walt Sanders <wsanders99@earthlink.net>
Date Tue 10/8/2024 10:45 AM
To NPRM <NPRM@dea.gov>
Cc Richard Brumfield <richard.brumfield@gmail.com>; Greg Davenport <gdavenport@fullspectrumomega.us>; Guillermo Avina <gavina@fullspectrumomega.us>; David Serrano <drsmjrx@gmail.com>; John Frazier Glenn <jfglenn7997@comcast.net>; wsanders99@earthlink.com <wsanders99@earthlink.com>

Good Morning DEA Hearing officer,

Could you please inform our group of the current process and procedure for the DEA hearing on rescheduling on marijuana scheduled for December 2? Did you receive our request and when will the decision be made on the selection of witnesses who are approved to appear a the hearingaaaaaaaa/

Walt A. Sanders
President & CEO
Sanders International Group, LLC
5008 Dodson Drive
Annandale, VA 22003
(703)728-2431
wsanders99@earthlink.net

From: Walt Sanders [mailto:wsanders99@earthlink.net]
Sent: Thursday, September 26, 2024 3:53 PM
To: 'nprm@dea.gov' <nprm@dea.gov>
Cc: Richard Brumfield (richard.brumfield@gmail.com) <richard.brumfield@gmail.com>; Greg Davenport (gdavenport@fullspectrumomega.us) <gdavenport@fullspectrumomega.us>; Guillermo Avina (gavina@fullspectrumomega.us) <gavina@fullspectrumomega.us>; David Serrano <drsmjrx@gmail.com>; John Frazier Glenn (jfglenn7997@comcast.net) <jfglenn7997@comcast.net>; 'wsanders99@earthlink.com' <wsanders99@earthlink.com>
Subject: DEA Hearing Request

Dear DE A Hearing Officer,

Re: Docket No. DEA-1362

Attached is a request by Full Spectrum Inc. (FSO) to appear at the hearing in the matter of "whether marijuana should be transferred to Schedule III of the list of controlled substance 21 CFR 1308.42 on December 2, 2024 at 9 am at 700 Army Navy Drive, Arlington VA 22202.

Please let us know as soon as possible if our request is approved.

Walt A. Sanders
President & CEO
Sanders International Group, LLC
5008 Dodson Drive

Annandale, VA 22003
(703)728-2431
wsanders99@earthlink.net

From: jfglenn7997@comcast.net [mailto:jfglenn7997@comcast.net]
Sent: Thursday, September 26, 2024 12:51 PM
To: Walt Sanders <wsanders99@earthlink.net>
Cc: Richard Brumfield <rbrumfield@fullspectrumomega.us>; Guillermo Avina <gavina@fullspectrumomega.us>; Gregory Davenport <gdavenport@fullspectrumomega.us>
Subject: Final approved DEA Hearing Request

Walt,

Please submit the attached per the instructions provided in the announcement.

Confirm when complete.

Thanks!

Best,
Frazier

Outlook

FW: Docket No. DEA-1362

From NPRM <NPRM@dea.gov>
Date Wed 10/9/2024 12:36 PM
To Riggs, Jessica M <Jessica.M.Riggs@dea.gov>

From: Jeffrey Faatz <jeff.faatz@gcpclinicalconsultants.com>
Sent: Monday, September 30, 2024 7:44 PM
To: NPRM <NPRM@dea.gov>
Subject: [EXTERNAL] Docket No. DEA-1362

To whom it may concern:

I would like to participate in this hearing, which is scheduled to occur on December 2, 2024, at 9 a.m. ET at 700 Army Navy Drive, Arlington, VA 22202.

I would like to give firsthand testimony on the detrimental effects of modern marijuana, particularly the high concentration liquid and wax formulations. The potency of modern marijuana destroys lives and families, and it should not be rescheduled unless, and until, randomized, controlled clinical trials demonstrate safety and efficacy for certain indications in certain populations.

I look forward to attending the hearing.

Sincerely,

Jeffrey A. Faatz
President & Principal Consultant

Image
Market Street in The Woodlands
9595 Six Pines Drive, STE 8210
The Woodlands, TX 77380-1586

E: jeff.faatz@gcpclinicalconsultants.com
P: +1-936-230-0046
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In Matter Of: Schedules of Controlled Substances: Rescheduling of Marijuana.

Docket No. DEA-1362

21 CFR, Part 1308.

To:

Agency: Drug Enforcement Administration, Attn: Administrator

8701 Morrissette Drive, Springfield, Virginia 22152.

Action: Notice of the Proposed Rulemaking, Notice of Appearance

SUMMARY

The Department of Justice ("DOJ") proposes to transfer marijuana from schedule I of the Controlled Substances Act ("CSA") to schedule III of the CSA, consistent with the view of the Department of Health and Human Services ("HHS") that marijuana has a currently accepted medical use as well as HHS's views about marijuana's abuse potential and level of physical or psychological dependence. The CSA requires that such actions be made through formal rulemaking on the record after an opportunity for a hearing

ISSUE

The Honorable Anne Milgram

Dear Administrator,

The undersigned Mr. John Jones hereby requests the assistance in the in-person hearing in the matter of: Notice of the Proposed Rulemaking in conformity with the requirements of 21 CFR, Part 1308 and 21 CFR Subpart D, § 1316.48.

On behalf of Cannabis Bioscience International Holdings (CBIH), we are writing to express our full support for the Department of Justice (DOJ) proposal to reclassify marijuana from Schedule I to Schedule III of the Controlled Substances Act (CSA). We align with the Department of Health and Human Services (HHS) in recognizing marijuana's accepted medical uses. We are committed to collaborate in order to endorse this proposal and participate in the in-person hearing.

As a company dedicated to developing medically significant formulations based on cannabinoids for treating prevalent diseases, we are keenly aware of the robust scientific

evidence supporting the therapeutic potential of cannabis-derived compounds. These compounds have demonstrated effectiveness across various conditions such as cancer, epilepsy, neurodegenerative diseases, osteoarthritis, psychological disorders, glaucoma, and metabolic syndromes. The benefits of these treatments are backed by numerous clinical studies and patient experiences, where cannabis has proven to be a safe and effective therapeutic option, significantly enhancing quality of life and well-being. We strongly advocate for the clinical, medical, and pharmacological importance of marijuana in advancing safe and effective treatments for diseases that impact the population.

We are keen to participate in this hearing to present scientific studies and clinical trials validating the therapeutic benefits and pharmacological potential of natural compounds derived from *Cannabis sativa* L., or marijuana. Despite historical stigma and barriers to medical use, our goal is to demonstrate how these compounds effectively treat various conditions. We support the embracing and exploration of marijuana's medical applications, backed by substantial research, to broaden treatment options and improve patient outcomes.

Cannabis differs significantly from highly addictive opioids like morphine, oxycodone, and fentanyl, which have caused widespread dependency and a public health crisis despite their effectiveness in pain management. In contrast, cannabis use generally leads to minor side effects such as slight dizziness or mild euphoria, making it a safer therapeutic option. Medically supervised cannabinoid use provides an effective alternative for pain management and other medical conditions without the substantial addiction risks associated with opioids.

It is important for public health policies to reflect this distinction and support rescheduling cannabis to a level that allows for broader medical use and research.

Moreover, cancer represents a significant global health challenge, ranking as the second leading cause of death worldwide with millions of lives lost annually. It affects individuals across all demographics and regions, imposing a substantial health burden that requires continual advancements in prevention, diagnosis, and treatment strategies. Efforts to improve early detection methods and develop effective therapies are critical in combating this pervasive disease.

Cannabinoids show promising anticancer effects in breast, pancreatic, prostate, lung, and liver cancers. They inhibit tumor growth and metastasis by reducing cell proliferation, inducing apoptosis, and enhancing chemotherapy efficacy. These actions are mediated through interactions with the endocannabinoid system, suggesting cannabinoids as valuable in cancer treatment.

Furthermore, cannabinoids in cancer treatment provide a unique advantage by protecting healthy cells compared to traditional chemotherapy and other drugs. Unlike conventional treatments that often harm healthy tissues along with cancer cells, cannabinoids have demonstrated a preference for targeting cancer cells while leaving normal cells relatively untouched. This selective action underscores the importance of ongoing research to develop safer and more effective cannabinoid-based treatments for cancer and other diseases.

Additionally, further clinical studies are essential to fully grasp the therapeutic potential of cannabinoids across various diseases. However, preliminary research and anecdotal evidence indicate promising avenues for exploration. Incorporating cannabinoids into treatment strategies for diverse conditions could introduce novel therapeutic options aimed at alleviating symptoms and potentially halting disease progression.

Rescheduling marijuana to Schedule III will not only facilitate scientific research and the development of new medical treatments, but it will also contribute to a more effective and safer regulation of its medical use, benefiting patients and healthcare professionals.

Thank you for your attention, and we remain at your disposal for any further inquiries.

Respectfully yours,

John Jones
Treasurer and Director
CBIH

Equity Trade Network
2261 Market St. #4
San Francisco, CA 94114

Drugs Enforcement Administration
Attention: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Request for Public Hearing on Docket No. DEA-1362

To Whom it May Concern,

We are writing to formally submit a request for public hearing. As we read the proposed rulemaking in Docket No. DEA 1362 Sect.X.5, it was clear that there was a lack of understanding and a desire for testimony from small businesses in the cannabis industry and how these rules would impact our businesses.

The Equity Trade Network is a small business ecosystem of over 40 businesses owned and operated by Black, Brown, Indigenous, LGBTQ, Veteran or system-impacted people from all over the United States of America. Many of us have transitioned from the non-regulated into Equity Programs and have struggled to stay afloat and keep up with heavily regulated, and often very complicated, state frameworks.

We have had to organize because the intention of social equity and economic opportunity has not come to fruition. The aforementioned regulations have created such a hostile landscape for small businesses to be able to gain a stable footing. This is true true for countless small businesses in America, especially in Black and Brown communities, not just in cannabis. Our Mission is to increase economic sustainability and to heal our communities from the consequences of the War on Drugs by uplifting the voices of our members' lived experience and supporting their businesses by advocating for increased opportunity to funds and reduced barriers to entry.

Weparticipated, in good faith, in the Legalization Movement in hopes that we could contribute to the economic development of communities devastated by disproportionate enforcement of full cannabis prohibition. We are concerned that moving cannabis to schedule III would allow the DEA to continue enforcing cannabis laws unjustly, under the guise of regulation. Docket No. DEA 1362 clearly states that "If marijuana is transferred into schedule III, the manufacture, distribution, dispensing, and possession of marijuana would remain subject to the applicable criminal prohibitions of the CSA.", giving the DEA full enforcement power once again. Though we see the value in recognizing the medical value of cannabis at the state level, we know from experience that government regulation in this sphere does not have the best track record in

protecting impacted communities. Further, this does not expunge records or release those incarcerated for cannabis related sentences, which is a critical aspect of true decriminalization.

Relief from the IRS Tax Code 280e is imperative for the survival of our businesses but we are not willing to sacrifice the progress Social Equity has made; moving to Schedule III still leaves our consumers and small businesses at risk of being recriminalized.

Equity Trade Network is in full support of Descheduling cannabis and to continue our good faith effort in progressing the conversation on how the United States can repair the harms of the War on Drugs.Furthermore, it is important to provide health and safety provisions around access to clean, tested cannabis products that can optimize the positive benefits of the plant for both medical and adult-use, and as a dynamic agricultural product .

Thank you for your consideration and look forward to your continued participation in the evolution of this conversation. Please consider us, and our members, as a valued voice and asset at the table.

Sincerely,

Leah Weitz
Co-Founder
The Equity Trade Network

Public Comments on DEA Rescheduling of Cannabis Decision
[Docket No. DEA-1362]

To Whom It May Concern,

I am writing to express our position on the DEA's proposed rescheduling of cannabis as outlined in the Federal Register on August 29, 2024 (Docket No. 2024-19370). We have a vested interest in this proceeding as the rescheduling of cannabis will significantly impact the regulatory framework, data collection, public health policy, and educational needs surrounding cannabis-derived products.

Interest in the Proceeding

Our efforts focus on health care provider education, public health research, product development, and patient care. The decision to reschedule cannabis will directly affect our operations, particularly in how cannabinoid-based products are regulated, produced, tracked and how that data is collected and accessed. With the number of potential cannabis and hemp product variations exceeding 1.5 million (due to different forms, formulations, and ingredients), rescheduling cannabis will influence the safety, standardization, and oversight of this diverse product market.

Objections and Issues of Concern

While we appreciate the DEA's efforts to modernize cannabis policy, we wish to raise the following issues:

1. **Lack of Systematic Data Collection**
   With millions of product variations in the cannabis market—ranging from edibles to vapes, oils, and topical creams—the absence of consistent product tracking and data collection mechanisms presents a major public health concern. Assigning standardized product codes similar to National Drug Codes (NDCs) to cannabis products is essential for their proper inclusion in medical records, which will enable healthcare providers and regulators to monitor safety and efficacy. Without such standardized tracking, the rescheduling process will lack the structure needed for effective regulation.
2. **Inconsistent Regulatory Framework for Hemp-Derived vs. Cannabis-Derived Cannabinoids**
   The regulatory divide between hemp-derived and cannabis-derived cannabinoids must be addressed. We advocate for a unified regulatory framework that treats these substances under a single scheme. This would promote consistency in product safety standards and better protect consumers while fostering innovation in the industry.

Position Regarding the Objections and Issues

While we support the DEA's decision to reschedule cannabis, we believe it is crucial to address these concerns:

1. **Data Collection and Product Tracking**
   Assigning NDCs to cannabis products will ensure that these products are properly tracked, allowing for consistent data collection on product types (e.g., inhalable, edible), formulations, and concentrations. Given the vast array of product variations—estimated to be over 1.5 million—systematic tracking is critical to ensuring public safety and advancing research. Implementing a standardized data collection form for cannabinoid products similar to the collection of alcohol and smoking consumption would enhance the understanding of the true benefit/risk and abuse potential of cannabinoids.
2. **Unified Regulatory Framework**
   We strongly recommend that hemp-derived and cannabis-derived cannabinoids be regulated under the same framework. This will ensure consistency in quality and safety standards, making it easier for regulators, consumers, and industry stakeholders to navigate this complex market.

In conclusion, we only support this rescheduling on the condition that a system is in place to collect data and monitor efficacy and adverse events in the context of product details. Without these measures, the rescheduling process risks being ineffective and could lead to inconsistencies in public health protections and product safety. We believe the DEA's success at rescheduling cannabis hinges on implementing a robust data collection system and a unified regulatory framework that treats all cannabinoids equitably.

Thank you for considering our comments.

Jahan Marcu, PhD
Teresa Simon, MPH
Phil Molloy, MD

MARIJUANA AS MEDICATION AND CURRENT SCHEDULING

Schedule I means there is a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 USC Section 812.

Definition of medication:

To approve a medicine, the FDA requires five criteria to be fulfilled:

1. **The drug's chemistry must be known and reproducible**.

Dispensary marijuana contains highly variable THC content, variable ratios with CBD, highly variable delivery systems and potencies, as well as several hundred other molecules of the plant, many of which may have activity on the human body. Standardization, content, product integrity, and product shelf-life are REQUIRED by the FDA.

Due to this alone, reproducibility of dispensary cannabis products is extremely difficult in the scientific arena. Current cannabinoids available as medicine include dronabinol, nabilone, and cannabidiol. Dabs, waxes, butane hash oil, shatter, cannabis vaporizers have not met scientific rigor, are highly potent, and potentially dangerous.

2. **There must be adequate safety studies**.

"Dispensary marijuana" has not been studied or used safely under medical supervision since the substance, and its components have not been standardized. It is accepted that use of marijuana may impair ones ability to drive, memory, cognition, and balance, among other potential effects. Extended use, particularly with higher potency products may cause psychosis, excessive vomiting (hyperemesis), anxiety, addiction, among other potential harmful effects.

Due to the lack of standardization, which includes dosing guidelines, wide spectrum of potencies and content, and the lack of high quality scientific study, the safety of dispensary marijuana is currently unknown.

3. **There must be adequate and well-controlled studies proving efficacy.**

There is conflicting information on the efficacy of dispsensary cannabis. Current FDA approved cannabinoids such as dronabinol, nabilone, and purified cannabidiol, have specific and proven indications. These medications have a package insert, which educates the consumer on the risks of taking these particular medications, whereas dispensary marijuana does not. For example, FDA-approved cannabidiol clearly states in its package insert, the risk of liver damage, suicidal behavior, and sedation and is approved for a narrow spectrum of pediatric seizures.

Studies on dispensary marijuana is generally fraught with poor quality studies with a high risk of bias and commonly are of short duration with a smaller number of subjects. The high variability of dispensary marijuana makes scientific study more difficult, despite the fact that there has been over $3.5 billion dollars spent on studying marijuana and over 30,000 scientific papers generated. There are no studies of raw marijuana that include high-quality, unbiased, blinded, randomized, placebo-controlled or long-duration trials.

4. **The drug must be accepted by well-qualified experts**. Medical associations generally call for more cannabinoid research but do not endorse marijuana as a medicine.

Here is a short list of some of the organizations which do not endorse the use of marijuana as medicine.

American Medical Association
"Cannabis is a dangerous drug and as such is a public health concern"
American Psychiatric Association
"No current scientific evidence that marijuana is in any way beneficial for treatment of any psychiatric disorder … the approval process should go through the FDA."
American Heart Association
American Lung Association
American Cancer Society
American Academy of Pediatrics
American Academy of Neurology
American Society for Addiction Medicine
IASP

5. **Scientific evidence must be widely available**.

Although there has been extensive study on marijuana it still has not become mainstream in terms of medical education. Dispensary marijuana is difficult to study given the problems already discussed.

To reside in Schedules II-V and be approved for diagnosing, mitigating, treating or curing a specific medical condition, a substance or botanical must proceed through a rigorous FDA scientific process proving safety and efficacy. Not one form of "dispensary marijuana" with a wide range of THC levels and potencies— butane hash oil, smokables, vapors, edibles, liquids — has gone through this rigorous process for a single medical condition

Should we dismiss heartfelt appeals from people suffering various diseases, self-reports of safety and effectiveness for a myriad of symptoms, and considering that many chronic, debilitating ailments are inadequately managed? Human stories should not be ignored, and rigorous, creative solutions can be formulated in response, including the use of FDA-approved purified cannabinoids at does ranges deemed relatively safe.

Marijuana fails to meet any of these five criteria for accepted medical use in the United States. At present, it belongs in Schedule I. Moving marijuana to Schedule II "to promote research" is unethical, as marijuana would then be designated a safe and effective medicine in the absence of high-quality evidence.

The FDA has warnings on "false medical claims"

False medical claims from cannabis and CBD companies. They are NOT allowed to make false medical claims (treating anxiety, pain, assist sleep, increase appetite (only

FDA-approved dronabinol can does this), cure cancer, anti-inflammatory, treat seizures (only FDA approved Epidiolex can do this), etc.

If you know a web page or tv or radio ads making false medical claims - send the information (web site, name of company, claim being made) to ALL 3 of the following sites:

badad@fda.hhs.gov

CAERS@fda.hhs.gov

druginfo@fda.hhs.gov

Medicine vs drug

All medicines are drugs but not all drugs are medicines
- There is an FDA drug development process
- Defined content
  - Dronabinol: CIII
  - Nabilone: CII

- National Center for Complementary and Integrative Health (NIH) has safety concerns about cannabinoids
  - FDA has NOT approved the cannabis plant for any medical use
  - FDA has NOT approved dietary supplements with THC or CBD
  - FDA has product integrity concerns
- Package insert not available for dispensary marijuana

ABUSE POTENTIAL

Marijuana has higher addictive rate than opioids, particularly with early onset
Earlier data 9% addictive rate in adult, current is 30% (NIDA)
Develop marijuana use disorder

American Drug Addiction Centers
Maranon
American Psychiatric Association
American Society on Addiction Medicine

HARM

1. In Utero exposures
   - Dispensary recommendations, Colorado
     - 70% of dispensaries in CO recommend women use in first trimester (N=400)
   - Connecticut data
     - MJ exposures most common substance (80%)
     - Opioids (20%)
     - Alcohol (<3%)
     - Avg. 6.6 babies per day

ABCD study
9-11 years of age: behavior problems, psychotic-like experiences, etc
NIH data
Problems persist into adolescence
Autism rates higher in MMJ states
Pediatric cancers

2. Psychosis/Suicide
MJ most common substance found in completed teen suicide in CO
5 fold increase in first time psychosis (European data, lower potency)
Up to 30% of schizophrenia cases could have been prevented (Danish study)
6 million people over 50 years
Cannabis use a well-established risk factor for psychosis

3. Pediatric poisonings
13 fold increase of children ending up in the ED from exposure
4% end up on a ventilator
20% with central nervous system
Virginia death related to Delta-8 in 4 yo boy

4. Elderly poisonings
18 fold increase in elderly presenting to ED with cannabis poisonings
Drug-drug interactions
CBD has 576 drug interactions
Liver damage
Suicidality
Sedation (FDA warnings on driving as well as integrity)
SAMHSA warnings on CBD; reproductive effects

5. Product integrity
State of Oregon audit report 2019
Colorado product recalls
California fail rate
Washington has had product recalls (pesticides)

ROUNTREE
CONSULTING

Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Attn: Administrator

Cc:
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Attn: Hearing Clerk/OALJ

Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Attn: Register Representative/DPW

Re: Request for Hearing
Docket: DEA-2024-0059
Position: Opposed

Dear Administrator,

I am writing regarding DEA Docket DEA-2024-0059, which concerns the Department of Justice's proposal to transfer marijuana from Schedule I of the Controlled Substances Act (CSA) to Schedule III. This proposal is based on the Department of Health and Human Services' (HHS) view that marijuana has a currently accepted medical use, along with considerations of its abuse potential and level of physical or psychological dependence.

I oppose this rescheduling due to the increased risks it poses to public health and safety. Accordingly, I hereby request a hearing.

300 S. El Camino Real, Suite 206, San Clemente, CA 92672
Phone (949) 366-3180 • Fax (949) 366-3181
www.rountreeconsulting.com

Statement of Interest

As a Certified Public Accountant (CPA) and a professional deeply involved in regulatory and compliance issues within the cannabis industry, I have significant expertise and a vested interest in this proceeding. My professional and personal experiences provide me with a unique perspective on the potential consequences of rescheduling marijuana.

Objections and Issues

1. **State Regulatory Failures:**
    - Many states have inadequate systems for tracking, recalling, and ensuring the safety of cannabis products.
    - Existing tracking systems (e.g., METRC, BIOTRAK) often fail to maintain comprehensive oversight, leading to issues with recalls and consumer safety notifications.
2. **Public Health Risks:**
    - The widespread use of marijuana, combined with insufficient state regulation, exposes consumers to significant health risks.
    - Black-market marijuana, often sold openly, poses dangers including exposure to pesticides, *harmful chemicals, and potential contamination with substances like fentanyl.*
3. **Organized Crime and Cartels:**
    - Illegal operations, including those run by cartels, dominate the cannabis market, using sophisticated methods to evade regulation.
    - Forced labor and deplorable working conditions are prevalent in these illegal operations.
4. **Loss of Enforcement Tools:**
    - Rescheduling marijuana would undermine critical enforcement tools like 26 U.S. Code Section 280E, which is vital for prosecuting illegal sellers and disrupting organized crime activities.

Position

Rescheduling marijuana from Schedule I to Schedule III would falsely reassure consumers of the safety of marijuana products, exacerbating public health risks and weakening regulatory oversight. It is essential that the DEA maintain stringent controls and leverage tools like 280E to combat illegal activities and protect public health.

300 S. El Camino Real, Suite 206, San Clemente, CA 92672
Phone (949) 366-3180 • Fax (949) 366-3181
www.rountreeconsulting.com

Request for Hearing

I request a hearing to present these concerns and provide detailed evidence and expert opinions on the potential adverse effects of rescheduling marijuana. An in-person hearing will enable a comprehensive discussion of these critical issues and ensure that all relevant facts and perspectives are considered.

Sincerely,

Michael D. Rountree, CPA, MBT
CA CPA 85364 / HI CPA 4488
300 S. El Camino Real, Suite 206, San Clemente, CA 92672
Phone: (949) 366-3180
Fax: (949) 366-3181
www.rountreeconsulting.com

Research Information:

1. State Regulatory Failures:
   - *California Bureau of Cannabis Control: Reports on recall inefficiencies and unregulated products. https://bcc.ca.gov*
   - *Cannabis Tracking Systems: Analysis of METRC and BIOTRAK systems' limitations. https://www.metrc.com*
2. Public Health Risks:
   - *Centers for Disease Control and Prevention (CDC): Statistics on marijuana use and associated health risks. https://www.cdc.gov/marijuana*
   - *Journal of the American Medical Association (JAMA): Studies on contaminants in black-market marijuana. https://jamanetwork.com/journals/jama*
3. Organized Crime and Cartels:
   - *DEA Reports: Documentation on cartel activities in the cannabis market. https://www.dea.gov*
   - *Oklahoma Bureau of Narcotics: Case studies on cartel involvement in cannabis operations. https://obndd.ok.gov*
4. Loss of Enforcement Tools:
   - *26 U.S. Code Section 280E: Legal implications and enforcement cases. https://www.law.cornell.edu/uscode/text/26/280E*

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Subject: Notice of Appearance

Dear Administrator:

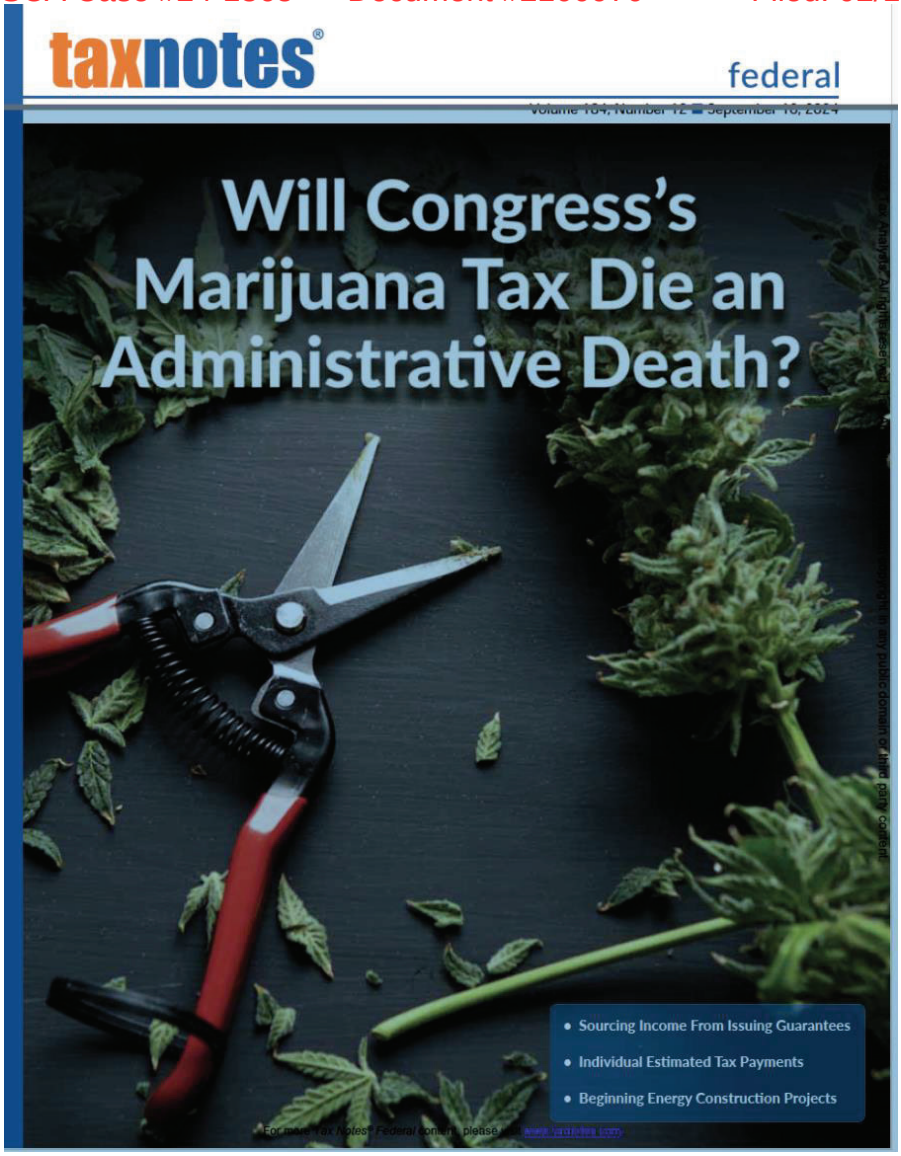
Please take notice that Patrick Oglesby would like to appear in the matter of the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act on December 2, 2024, as announced here: https://www.federalregister.gov/documents/2024/08/29/2024-19370/schedules-of-controlled-substances-rescheduling-of-marijuana

(1) State with particularity the interest of the person in the proceeding;

My interest in **tax policy** causes my interest in this proceeding – pro bono publico. The peculiar marijuana selling expense tax known as 280E would go away with Schedule III, since section 280E of the Internal Revenue Code, by its terms, burdens commerce only in Schedule I and II drugs.

You raised non-drug issues in your May announcement: "DOJ acknowledges that there may be large impacts related to **Federal taxes** . . . among other things. DOJ is specifically soliciting comments on the economic impact of this proposed rule." A secondary issue goes to economic impact -- the impact of a tax cut on the competitive positions of large and small cannabis businesses.

My analysis of the tax implications of rescheduling, "Will Congress's Marijuana Tax Die an Administrative Death?," was the cover story in the September 16 issue of Tax Notes magazine. https://www.taxnotes.com/tax-notes-federal/exemptions-and-deductions/will-congresss-marijuana-tax-die-administrative-death/2024/09/16/7l5lm.



I'm a former staff lawyer for the Joint Committee on Taxation and the Senate Finance Committee, and lead a tax policy non-profit, the Center for New Revenue, which has focused on the intersection of tax policy and drug policy. I have worked for various states and non-profits on cannabis taxation and economics, but **never** for the cannabis industry.

(2) State with particularity the objections or issues concerning which the person desires to be heard;

Because rescheduling would bring cannabis outside the ambit of Internal Revenue Code section 280E, which applies a special tax burden only to Schedule I and II drugs, my main issue is whether the Administration should **cut taxes** on marijuana businesses.

(3) State briefly the position of the person regarding the objections or issues.

For tax policy, I do not support Schedule III for marijuana. If you move away from Schedule I as inappropriate drug policy, Schedule II, retaining the 280E tax, would be more appropriate for tax policy than Schedule III. (I claim no expertise on non-economic matters, and have no opinion on whether Schedule II's "high potential for abuse and/or addiction" is more fitting than Schedule III's "low to moderate potential for abuse and/or addiction.")

A **federal marijuana tax seems desirable** and ultimately inevitable -- despite the state-legal marijuana industry's competitive struggles with the illicit market and with hemp THC drug sellers. Those struggles are vastly different among states, some of which have marginalized them. Meanwhile, for public health, the section 280E selling expense tax may be the best marijuana tax available. It nudges against advertising and marketing, which are often frills at best and demand-creators at worst. Schedule III would tax marijuana like tomatoes. In any realistic medium-term scenario, Congress would not tax marijuana like tomatoes.

A good marijuana tax is hard to find, so **it would be sad to see Congress's pro-public-health, revenue-positive section 280E selling expense tax die** by marijuana's administrative transfer to Schedule III. However, marijuana's transfer to Schedule II instead of Schedule III would keep the marijuana selling expense tax revenue coming in and would keep section 280E's unfinished tax experiment running.

I suggest that as you balance tax competing concerns, and that that balance tilts against Schedule III. Now the tax question is a close one, and your drug policy analysis involves much more than tax and economic issues. But I am glad that you are looking at those tax and economic issues, and **I hope my nuanced views will help you.**

Thank you.

All notices to be sent pursuant to this appearance should be addressed to:
Patrick Oglesby
po@newrevenue.org
919 619 8838
1830 North Lakeshore Drive
Chapel Hill NC 27514-6733 USA

Certificate of Service

I certify that this document was filed with the Court via the court's electronic filing system, on the 17th day of February, 2025, and an electronic copy was served on all counsel of record via the CM/ECF system on the same date. I further certify that I have mailed the foregoing document via first class mail, postage paid, to those parties or their counsel who are not registered through the CM/ECF system.

/s/Austin T. Brumbaugh
Austin T. Brumbaugh